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CIS

CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND LONG-TERM CARE

OF THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

FIRST SESSION

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CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

FRIDAY, JULY 19, 1985

House of Representatives,
Select Committee on Aging,
Subcommittee on Health and Long-Term Care,
Washington, DC.

The subcommittee met, pursuant to notice, at 9 a.m., in room 2318, Rayburn House Office Building, Hon. Claude Pepper (chairman of the committee) presiding.

Members present: Representatives Pepper, Oakar, Frank, and Skelton.

Staff present: Kathleen Gardner Cravedi, staff director; Melanie Modlin, assistant staff director; Peter Reinecke, research director; Mark Benedict, minority staff director; Patrick McCarthy, minority detailee; Glen Stettin, intern; Liz Gatti, intern; Catharine Wilson, intern; Eve Subrin, intern; Julia Kingston, staff assistant; and Melanie Pallone, staff assistant.

OPENING STATEMENT OF CHAIRMAN CLAUDE PEPPER

Mr. **Pepper**. The subcommittee will come to order.

The subcommittee is having a hearing on the subject of "Cataract Surgery: Fraud, Waste, and Abuse." One of our distinguished members, Hon. Barney Frank, of Massachusetts, has to leave very shortly, so I am pleased to invite him to make whatever statement he would like to make at this time.

STATEMENT OF REPRESENTATIVE BARNEY FRANK

Mr. **Frank**. I congratulate you for this latest in a series of effective actions you have been taking on behalf of all the people. It is especially relevant that we focus here on the question of fraud, abuse and waste, and particularly on the point that it is the elderly people and the needy elderly who are the victims of this fraud and waste, and not the perpetrators.

Too often, when people talk about fraud and waste in programs that help needy people, the impression is left, sometimes wittingly, sometimes not, that it is the recipients who are the abusers.

The recipients are sometimes portrayed as the wasters. What you are doing today makes it clear in the preliminary work that I have seen that the staff has done and the testimony I have read, it makes it clear that the needy are in fact much more often than not the victims of this sort of fraud and waste.

Obviously, no one thinks that any substantial percentage of providers are guilty of perpetrating the fraud. Those who are abusing are a minority in the provider area, but it is important to focus on the fact that it is the elderly people who are victimized here.

They are victimized in the individual case, and beyond that, when programs that may help pay for some of this care are discredited because of the amount of fraud and waste that is there.

The right to health, to eyesight, is so essential that I cannot think of a more important topic on which to focus the energies of the Subcommittee on Health Care, so I am delighted to be able to participate, and I apologize because of an unforeseen event demanding my time elsewhere, I am going to have to leave shortly.

But this is a subject in which I will maintain great interest and look forward to working with you in developing any necessary remedial legislation.

Mr. PEPPER. Thank you very much. We appreciate your being with us as long as you are able. We are, of course, deeply grateful for your keen interest in this subject.

Ladies and gentlemen, and members of the subcommittee, today's hearing has been called to explore allegations of fraud, waste, and abuse in cataract surgery in the United States. This subject is of immense concern to the people of this Nation, because a person living a normal lifespan is more likely to undergo a cataract operation than any other major surgical procedure.

Today, about 60 percent of all older Americans, or about 15 million older persons, have cataracts. About 1 million will seek surgery to correct this disabling and potentially blinding disorder at a total cost of over $3.5 billion. Fortunately, this operation, which is the most frequently reimbursed major surgical procedure under the Medicare Program, is almost always dramatically successful.

Technological advances have been largely credited with this miraculous vision-restoring procedure. I never had the operation, but I've heard about it. At first, patients had to lie immobile for 2 or 3 days between sandbags to keep them from turning their heads. The only other option for cataracts was to be fitted with thick, heavy glasses to help restore vision. Today, about 70 percent of all patients getting cataract surgery spend about 3 hours in a hospital or doctor's office following a 20-minute operation in which a small intraocular lens, or "IOL," is implanted.

What a wonderful achievement, and how grateful we are that we have achieved that wonderful advance in scientific knowledge and procedures.

Today, 85 percent of all cataract patients have an IOL implanted following cataract surgery. Let me show you what an IOL looks like. You see this little red circular material that I hold in my hand? In the center is the meaningful part, which by surgical procedure is implanted in the eyeball and immediately restores complete vision of the individual fortunate enough to receive it.

We are told that this tiny vision-restoring device, an IOL, costs only about $50 to manufacture. All credit to our manufacturing and management skill, which makes it possible to turn out a very fine piece of work like that for a relatively small amount, $50. Yet, our investigation reveals that Medicare is reimbursing doctors and hospitals an astonishing $300 to $750 apiece for it. It is precisely for this reason and because of other current Medicare reimbursement practices that we are holding today's hearing, in which we will report that approximately 50 cents of every dollar the taxpayer spends for cataract surgery, or about $2 billion, is lost to fraud, waste and abuse.

I don't have to tell you what it means to have one's vision. Imagine what a dreary world it would be to any of us if our vision was taken away, and we had to stumble and fumble our way around. Imagine not being able to see all of the things with which we are in contact in our daily lives.

What a godsend it is to have this simple little device, the IOL, which should be relatively inexpensive, available to restore that God-blessed faculty that the human normally has, the ability to see.

All we are saying here today, we don't think anybody should exploit people attempting to recapture their failing vision.

I would like to have inserted at this point in the record a copy of our report, documenting the results of an investigation by our subcommittee. This investigation is the result of 2 years of work by the staff of our subcommittee.

[See app. 1 for the report submitted by Chairman Pepper.]

Mr. PEPPER. It highlights, for those who read it, the major findings that we have made in this study. We will officially file it at this time, and invite all to examine it who will.

First, Medicare will waste about $1.2 billion in 1985 in cataract surgery alone. As I mentioned, technological advances have reduced this procedure from a 23-day stay to a 3-hour visit to a hospital. This, combined with hospital cost containment or the new DRG system, has contributed to the majority of such procedures being performed on an outpatient basis. You go in and have the surgery performed as an outpatient. One would think that this shift to outpatient surgery would result in a savings to the Medicare Program, as valuable hospital resources, nurses, rooms, et cetera, would be eliminated. We found this not to be the case. Medicare pays no less than $2,400 for cataract surgery performed in the hospital where the costs are controlled by the new DRG system. When the same procedure is performed in the same hospital on an outpatient basis, Medicare is paying several times this amount—as much as $5,700. We think that is unconscionable, to implant something that costs the manufacturer about $50.

The manufacturer is entitled to a fair profit. What is a fair profit? Is that a fair profit, 100 percent? That would make it cost $100 to the patient.

When you have the surgery outside the hospital, you are not using the room, electricity, air-conditioning and so on. The patient comes in and has the operation performed in a little bit and leaves. With a price tag of $5,700.

That money, that money Medicare is spending, is money available to help people who are sick, who are ill. There are just a lot of illnesses, very serious in nature, like Alzheimer's disease, that are not covered by Medicare.

That is not an inexhaustible supply of free money that you pick up like manna from heaven in the desert. That is money that is paid in by employers and employees to provide medical care to people who are ill.

Every time you take an extra dollar that could be saved from that fund, and it's lost to waste or fraud you are not robbing the U.S. Government, you are really robbing somebody else that is sick who really needs that money. So as I say, they pay on these outpatient cases as much as $5,700, for using only three hours of hospital resources. While the DRG system was intended to reduce medicare costs by putting a limit on the amount paid for services provided in a hospital, the same rules do not apply to outpatient services, or part B of Medicare.

In America, is the profiteering motive so strong, that if we don't have stringent government regulations, people will abuse the private enterprise system and charge every penny they can gauge out of those from whom they can get it? That does not seem to be in accordance with the American spirit, and what should be the American way of life.

Another factor fueling fraud, waste, and abuse in cataract surgery relates to the price of the IOL. As mentioned, it costs about $50 to make an IOL, this tiny piece of plastic, but it is reimbursed by medicare at $300 to $750 a piece.

You can calculate what percentage of profit that is. If it costs $50, that is from 10 to 15 times what it costs, if they charge $500 to $750 for it.

Under the DRG system, many hospitals have gone to competitive bidding, reducing IOL prices by about 50 percent or more, so they sometimes cost less than $100 apiece. Where outpatient surgery is performed, there is no corresponding pressure to reduce IOL prices because Medicare pays the reasonable cost ranging from $300 to $750. It is obvious that the profit margins are very high and that some manufacturers are trying to stave off true competitive bidding by taking $50 to $150 or more out of their profits to buy off some physicians and gain a competitive edge.

One of the most shocking things happening in America today is the disregard for the simple principles of honesty, morality and decency that we find so frequently revealed.

Institutions of great repute and prestige who have enjoyed public confidence are found to be ripping off innocent people with whom they have an opportunity to deal, and in instance after instance, people on the inside are defrauding the companies, and the people, and now we find that the profit motive has become so strong in cases that will be revealed to you today, that they have offered bribes to doctors, to induce doctors to use a particular kind of instrument, a kind of an IOL.

It is a sad story. It looks like there is some laxness in what we thought were the typical American principles of decency and honesty and integrity.

The subcommittee found that evidence of improper inducements, kickbacks, and other illegal marketing practices is flagrant and inescapable. Inducements ranged from outright payments of cash to physicians, in the form of $50 deposits in secret Cayman Islands bank accounts for each lens purchased, to free stock in the manufacturer, free lasers and other IOL surgery equipment, the donation of one lens for every one purchased, keys to resort condominiums, yachts, cars and houses, trips to Colorado, Europe, et cetera, for medical skiing seminars and large payments for phony consultant work and to FDA investigators. Large donations to the physician's favorite charity or personal research foundation by IOL representatives were also uncovered. Our investigation confirmed the judgment of one physician who told the subcommittee:

> The whole system is corrupt and corrupting physicians, mostly I feel, out of ignorance, but of course, greed is a factor. Some very big names in ophthalmology are receiving large financial incentives to PR the companies' implants. I am happy to see you investigating this and though it casts a shadow on my profession, if we can stop the 20 percent or so who are unethical it may restore people's faith in my profession.

We found that about half the price of each lens is lost to fraud and improper inducements, resulting in a loss to the Medicare Program in 1985 of about $160 million.

Finally, we found that 23 to 36 percent of all cataract surgery may be unnecessary. This is another very shocking thing. Many Americans may show signs of cataract but have no functional impairment. It is at this point in the decision process that unnecessary surgery may occur. We have heard of instances where elderly patients with 20-20 vision underwent cataract surgery. About $819 million will be lost to the Medicare Program and cataract patients due to unnecessary surgery in 1985. Of this amount, $525 million will be lost by the Medicare Program alone.

We heard of one instance where one of these doctors using this technique advertised to truck drivers, that he could make them see better at night, and so in spite of the fact that they had 20-30 or even 20-20 vision, he gave them one of these cataract operations, and told them it would help them see better at night.

It didn't, of course, do any good at all.

During the course of its inquiry, the subcommittee also solicited the views of ophthalmologists and IOL manufacturers. Doctors, representing over 1 million patients, wrote us and confirmed our findings. One-third of these doctors told, us they had been offered lucrative gifts in return for purchasing their IOL's. Most found these offers distasteful and an embarrassment to their fine profession. Sadly, however, others did not. One doctor told us, "It is the American way. You get what you can." Another wrote, "These practices cheat Medicare and the patients, putting personal profit before the welfare of the patient."

Has fraud and conspiracy, become the American way? That is not the majority opinion of the doctors and the people. Unfortunately it is the few who stain the integrity of the many.

Less than 20 companies manufacture IOL's. About half this number responded to the subcommittee's survey. They, too, confirmed the existence of widespread fraud and abuse. While most of these companies expressed their distaste for such inducements, they also painted a picture for us of a highly competitive business, and lucrative, too. This is a work where salesmen earn an average of $35,000 to $90,000 a year and one in which, in the words of a particular company, "If you don't offer these discounts, you are likely to lose the customer."

The results of the subcommittee investigation will be forwarded to the Office of the Inspector General where it is felt followup action is warranted.

Today, we will hear from several ophthalmologists who will be able to describe for us firsthand the nature of these scams, which range from sophisticated and unethical to blatantly illegal.

In addition, I look forward to the testimony of the Inspector General, who will report to us his findings of a parallel investigation which I understand found widespread fraud and waste, confirming our conclusions.

One last point should be made. Medicare and the government encourage discounts, rebates, and other bonuses, as long as these reductions are passed on to the Medicare Program and the consumer. As this hearing and report will amply demonstrate, this has not been the case with cataract surgery.

I thank you for coming and look forward to the testimony we are about to receive.

I thank you for the opportunity to acquaint the public with these conditions we found and hope they may cease to exist or be very materially eliminated.

Now, we have two doctors whom we will call, and one of them is Dr. X, an ophthalmologist from California, and he will be accompanied by Dr. Y from South Dakota.

Dr. X, you may proceed.

PANEL ONE—THE PROBLEM: FRAUD, WASTE, AND ABUSE: CONSISTING OF DR. X, OPHTHALMOLOGIST FROM CALIFORNIA, DR. Y, OPHTHALMOLOGIST FROM SOUTH DAKOTA, AND HON. RICHARD KUSSEROW, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC, ACCOMPANIED BY BARRY STEELEY, STAFF PERSON

STATEMENT OF DR. X

Dr. X. I guess I am Dr. X. I have been in the private practice of ophthalmology for 16 years, and serve at a major medical school university as assistant clinical professor.

The purpose of me coming here was in response to a questionnaire that was sent by your committee, and there have been a few instances in the last few years where I have been approached by lens manufacturing companies offering me special kinds of plans, and I will outline those.

The first one was blatant, a lens manufacturing company who offered me a kickback of $75 for every implant I would use of theirs to an account in the Bahamas.

When I questioned him about the ethics involved, he handed me a paper from his lawyer for the company and said that this was a perfectly legal thing to do.

I was obviously very skeptical about this lawyer's opinion, and told him to forthrightly leave my office.

Recently, I have also experienced more subtle methods of kickback arrangements, and one was I bought a very expensive endophilial cell camera and was told by the company, if I use their implants and purchase them myself, that a considerable amount of the cost of the equipment that I bought would be underwritten by such an arrangement.

I have also been offered by various lens companies to either do core studies for which I would be paid a certain amount, approximately $100 or $125. If I didn't want to do the core studies, I didn't have to.

It was sort of, I felt at the time, a disguised kickback, because there are so many cores that are needed and if they are continuing the cores ad infinitum, it becomes a kickback arrangement, and I think that this is widespread.

I have an opportunity to get the pulse of what is going on in southern California to some degree by some people I know who are in the industry, and it is their opinion, and this is merely hearsay, that there are a large number of doctors, ophthalmologists, who are in one way or another participating in some type of an arrangement as I have just outlined, whether it be for equipment, or actual cash payment or some other advantage.

What happens then is that lense companies who do not offer those kinds of rebates feel at a disadvantage because they have lost some of their competitive edge, especially with those doctors who are anxious to reap the benefit.

One thing I have to mention is that this certainly is not the majority of the profession, I am sure, but I think that there is an unholy, you might say, arrangement going on between the manufacturing industry, for which I think ophthalmologists have in the past been a bit naive about, and by big business coming in, and you might call it a corruptor-corruptee relationship.

And these things are offered and perhaps out of naivete or whatsoever, they sound attractive and are easy to fall in. Anything that can be done, which may have to be done in a legislative way, something has to be done to eliminate this kind of practice, because it stains our reputation as a profession and pretty soon, we will be looked upon as lawyers.

I feel strongly about it. I think there are ways to handle it. I have some strong opinions about that, but I will hold them in arrears right now.

Mr. **Pepper**. Well, Doctor, we thank you very much for giving your testimony and trying to help us try to clean up this situation.

Do you think that this practice of trying to induce doctors to use particular IOL's by paying a special amount, in order to get them to do so, is a fairly general practice, or is it just an occasional thing?

Dr. X. I think it is widespread. I don't think it affects every doctor, but every doctor who is fairly busy, I would place, and this is a guesstimate, but any physician who does more than 300 implants a year would probably sometime in his practicing life be approached by someone.

The doctors who are less busy are less inclined to get these offers.

Mr. **Pepper**. Has the ophthalmological profession, the medical fraternity, I guess, has it taken any steps to try to prevent this kind of thing?

Dr. X. The American Implant Society has written some very strongly worded statements about this, especially fairly recently in regard to the dangers involved in any type of kickback arrangements that are going on, and this, I think, is making some effect or should have some effect.

I really feel that stronger types of inducements to end this practice will have to come from a higher authority, perhaps yours.

Mr. **Pepper**. Doctor, could you mention or just name any figure that you think might be reasonable, I mean, how much we could save if we could eliminate these practices that we are talking about, and there were only a fair charge for the cataract operation, including the purchase of the IOL?

Dr. X. I have given some thought to this, and this is purely my own conjecture, but basically, the cost to a hospital for an implant is anywhere from $200 to $400, and most institutions get a little profit which will range anywhere from $450 to $750, and this is the cost of the implant to the insurance carrier, Medicare mainly.

Within this cost of the manufacturer is the whole investigative form to the IRC committees, their whole investigation to the Government in regards to the safety of the implants, so they have some costs induced in there.

My feeling is that some limit on the payment of the implant would do several things, and it would solve the problem in my opinion.

Coexisting with that, something has to be done to streamline this investigative reporting, because it really is a meaningless study mostly, in my opinion. At present, there are core studies going on on every new type of implant that comes out, and it takes forever and a year for all these things to finally reach premarket approval, so the lens is considered safe.

Within the process, in my opinion, this could be speeded up, where you would have a core study for 500 implants, and then you would say any adverse reactions after that, and that would be very simple.

That would save the companies a great deal of money so they could charge less for the implants. Along with that, the profit that the hospitals get can be reduced. If there are going to be a million implants done in the next fiscal year, the average cost to the Government has to be around $500 per implant, we are talking over $500 million.

I would guess that maybe 20 to 50 percent of that could be cut out. I think it is expensive, so you are looking at a potential savings to the insurance carriers of perhaps $200 to $250 million.

If you took the necessary steps to speed up the whole investigative process, make it simple, clean, and just say, this is all we are going to pay, then there wouldn't be so much money floating around for these trips to the Bahamas and the Cayman Islands.

Mr. **Pepper**. Doctor, you heard my reference to the higher charge ordinarily made for outpatient service in the performance of the cataract operation, more than the amount paid ordinarily for a hospital patient.

What is the reason for that, and is there any justification for it?

Dr. X. That hasn't been my experience. A brief example, I led a fight a few years ago in my own hospital to try to get them to take assignment and reduce their costs and the hospitals generally charge anywhere from, the hospital bill could be anywhere between $2,200 or $2,500 per outpatient visit.

Outpatient surgical arenas are usually a little less. That has been my experience in southern California.

What happens is, they just base it on the costs plus and get whatever medicare will pay in the hospital setting, so it has been my experience that the system saves money in the outpatient surgery system, or surgery center, so it has been the opposite of what you mentioned.

Mr. PEPPER. Doctor, you see how unfair it is to the public, and also unfair to the Congress. We get complaints when there are excessive charges to the public funds like Medicare for medical care, but we are not experts in running a hospital.

Very few members have ever had anything to do with the management of a hospital, and this case right here looks like excessive charges are being made for both the hospital and outpatient care. And yet, unless the Congress does something about it, the abuse goes on. Recently, we have tried several experiments to try to bring down costs in hospitals, and one of them was a rather questionable method, I thought. Many doctors felt the same way about it, at least the dean of the Harvard Medical School expressed himself that way to me.

Namely, we adopted a rule that a hospital has to charge the same amount for the same disease that is treated in every patient. As the doctor pointed out, an elderly man comes in with a bad case of pneumonia, and a young man with a light case, and the hospital has to charge the same amount for treating those two people. This practice seems unfair, and that is the sort of predicament you get into, because we are not experts in how to control these costs, and the like.

Yet, people, by abuse, force the Congress to try to do the best it can to protect the public interest. It just shows how much better it would be if people involved in these private enterprises would be governed by some reasonable sense of propriety and economy, and give the benefit of those savings to the fund that can pass it on to many more people. That would save Congress from having to make what may be a sort of a blundering attempt to do it itself.

Well, Doctor, we are most grateful to you. I want my distinguished colleague, Mr. Skelton, to have an opportunity to ask any questions.

Mr. SKELTON. Let me ask you, Doctor, you have been discussing, as I understand, both abuses by the medical profession and by hospitals, is that correct?

Dr. X. Implant manufacturing companies?

Mr. SKELTON. Yes, sir.

Would you tell us again what abuses you can attribute to the medical profession in and of itself in this regard?

Dr. X. The abuses that the medical profession fall into are ones related to perhaps ignorance, and also to greed, and in order to be corrupted, you have to have a corrupter and there is a lot of money floating around in this business in regard to the implant business, and there are just some people, and like in any profession who cross over that gray line.

I don't believe it is a majority, but as I said before, the ones who are most targeted are the more busy ophthalmologists, so it is tougher on them to resist this, and it is a very subtle type of seduction.

Mr. SKELTON. Tell us how this so-called seduction comes about. Give an example, would you please?

Dr. X. As I previously stated, one company came to me and told me the attributes of their implants, and then mentioned that a certain sum would be put in an account in the Bahamas in my name.

Another was that, if I wanted to use their lenses——

Mr. SKELTON. Would this be per operation, per lens?

Dr. X. Per lens, that is correct. Another one was, I could do their core studies on a certain type of lens, or I didn't have to do a core study, but if I did the core study, I would be being paid a certain amount of money for the study which was over $100.

This is to fill out forms, and he said, you could have your nurse do that. This points out a tremendous problem. One is, the forms that are being used in the study are less than the most accurate thing in the world.

It has been reduced now to just a game of satisfying a bureaucrat in Washington.

Mr. SKELTON. It was an opportunity for them to pay the $100?

Dr. X. That whole study was an opportunity to make some money.

Mr. SKELTON. How much money did they offer to place in an account in the Bahamas?

Dr. X. I believe it was $75.

Mr. SKELTON. For each implant?

Dr. X. Right.

Mr. SKELTON. Should you have a willing physician to take them up on their offer, how much money could someone make in a month or a year?

Dr. X. Depends on how busy he is, but let me hasten to add, when I told this man that I thought that that was unethical, he produced an opinion from a lawyer, saying it was perfectly ethical, so believe it or not, there are some people who still look at a statement by a lawyer and believe every word of it.

I think that——

Mr. SKELTON. Both Members of Congress up here are lawyers.

Dr. X. I am sorry. I think there is a bit of naivete involved as well.

Mr. SKELTON. What would you attribute to the hospitals as an abuse in this regard, Doctor?

Dr. X. The hospitals' primary goal is to have a successful hospital that makes money, and they will use any means they can to do that and still provide good care, and as I briefly alluded to before, that in our particular hospital, I tried to have them reduce the costs to the cataract patient.

I will give you briefly an example. An outpatient cataract operation involves the patient being in the hospital less than 4 hours, use of the operating room for less than a half an hour.

The patient doesn't even get lunch. Yet, the cost involved is perhaps $2,500.

Mr. SKELTON. $2,500 for a 4-hour stay in the hospital?

Dr. X. You got it, but the real overhead costs were calculated by some people who do a lot of looking at this, and the real costs involved probably are in the range of $300 to $500, without the implant.

When you add the implant to it, then you have got to add whatever the cost of the implant is, and that is anywhere from $200 to $400, so when I approached the hospital to try to get them to change their ways, they wouldn't do it until a group of us got together and built a surgery center.

And as soon as we did that, they dropped their prices and all the hospitals in the area did so within this setting. This is what is called the American way, you try to make as much money as you can, and do the job, and that atmosphere is perhaps changing a little in the hospital arena, but I think that the real thing that is happening is that ophthalmologists who decided to go into the outpatient surgical thing have contributed to reducing the costs at least to the whole system, and by doing that one thing, forcing hospitals to reduce their prices.

So that is why it came as a surprise to me when Mr. Pepper mentioned that some outpatient centers were charging more than hospitals. The opposite has been my experience.

Mr. SKELTON. What are your recommendations, Doctor, to clean up this mess?

Dr. X. My feeling is that there should be a certain limit on how much you pay for implants. That would save a lot of money, and I don't know if that is a legal thing to do, but cut down the costs to you for the implants and those reductions would be passed down the line.

You have got to straighten out the whole investigative form business. It should be streamlined, the investigation process for implants, this new business, not new business, but this business about core and adjunct studies has to be reduced and simplified.

You have a certain number of core patients and after that report adverse reactions, so the lens companies don't have to have an internal bureaucracy to deal with the forms.

Those forms are not treated seriously by very many ophthalmologists.

Mr. PEPPER. Doctor, when I referred a moment ago in my questioning to outpatient service, I meant outpatient service in the hospital. Well, is it a larger charge generally for outpatient service in the hospital, than for inpatient services in the hospital itself, where they are subject to the DRG regulations?

Dr. X. The ones under DRG are reduced, that is true, but there is more profit made to the hospital because there is less overhead when it is an outpatient surgical procedure.

Mr. PEPPER. They charge more for an operation in the same hospital, but not a patient of the hospital as an outpatient?

It is also true, doctor, that some of these justifications for fees are based on conditions a good long while ago: 3 days in a hospital, maybe several hours for the operation to be done, whereas now, you skilled ophthalmologists can perform the operation in about 20 minutes, and the patient only has to stay a relatively short time in the hospital.

Is that true?

Dr. X. That is a fair statement.

Mr. **Pepper**. In other words, it looks like the Medicare fund and the patients should be getting the benefit of some of these economies that improve skill and conditions, but they are not getting them?

Dr. X. To some degree, they have happened, but it hasn't caught up, but the fact that you bring this to light might speed up the process.

Mr. **Skelton**. Mr. Chairman, were you through? I have another question.

Mr. **Pepper**. Go right ahead.

Mr. **Skelton**. Doctor, is it not true that as a result of what you have been describing to me, is it not true that there are a number of, or at least a possibility of a number of unnecessary implant surgeries performed?

Dr. X. Yes, no question about that. I don't know what the percentage would be, but I am sure that is the case.

Mr. **Skelton**. You will agree that there are a number of unnecessary cataract surgeries performed on senior citizens as a result of the procedure that you just described to us, is that correct?

Dr. X. Yes.

Mr. **Skelton**. What are the risks for a senior citizen? Should he or she have a cataract operation or implant that is unnecessary, what does this person risk receiving that unnecessary cataract implant?

Dr. X. It is probably one of the safest and most reliable of all surgical procedures around. Ninety-eight percent of the time, it is totally a happy event, but there are any number of risks involved.

I would say that they are under 2 percent, so that that is generally across the board. When you do unnecessary surgery, the patient is not going to see very well after surgery or will not get the necessary benefit, so it is easy to sell the operation.

Mr. **Skelton**. This senior citizen that doesn't have to have this surgery that you describe, runs a 2-percent risk of having some complications as a result of surgery, is that correct?

Dr. X. That would be my guesstimate.

Mr. **Pepper**. Doctor, this subcommittee has prepared and intends at an early date to introduce some legislation. I will just give you the gist and ask you if you have any comment to make as to whether that would appear to be desirable legislation.

First to cap Medicare reimbursements for outpatient cataract surgery. Second would be to cap medical care reimbursement for all types of outpatient surgery in this kind of case. Next, to require OTA to review a study of changes in technology and skill related to the implementation of any artificial device or organ, and to make recommendations to the Secretary of HHS, as to how Medicare payment for these procedures or devices might be revised downward to reflect the improvement made in techniques and the like.

And the last one would require review of all payments made by manufacturers to doctors for conducting what is called investigational studies of devices.

In other words, don't let that be too inviting an opportunity for false inducement. Have a reexamination of that to be sure that the payment that is made to the doctor for investigative work is not a bonus to the doctor for using a particular device.

Do they seem desirable to you?

Dr. X. Yes, on the surface, it sounds good.

Mr. PEPPER. Well, Doctor, thank you very much. You have been very kind to come and help us out.

Our next witness is Dr. Y, who is an ophthalmologist from the midwest. Doctor, we appreciate your statement.

STATEMENT OF DR. Y

Dr. Y. Mr. Chairman, members of the committee, good morning. I wish to thank you for inviting me to this hearing and for holding the hearing. I think you have a remarkable insight into some of these problems, and I think you are on the right track to solve some of them.

There is no question, as you say, that this business of cataract surgery has been a great boon to our senior citizens and the Medicare Program has made it available universally. It has been a great program.

The manufacturers, in their development of the intraocular lenses, have broadened the scope and horizons greatly and all manufacturers that I know of make an excellent product and have done a super job. And I must say that the FDA, in discharging its duties and conducting the largest study of any medical device and procedure, is to be commended.

Unfortunately, ethical ophthalmologists, which is the largest majority of them, and the ones I know certainly, have been shocked by some of the marketing strategies that a few of these companies have resorted to in efforts to protect and expand their market share.

If you make some structural changes in the system, you can eliminate these things, reduce them to some irreducible minimum, and that would be a good thing, because we don't want anything that is unfair to our patients or to the public going on. I speak for myself as an ethical ophthalmologist, and I am sure that the vast, vast majority of my colleagues feel the same way.

Some of the manufacturers do not, and have never been involved in this, and I think they deserve credit for that. I know one, the Precision Cosmet Corp. I mention that because people who do things appropriately deserve credit.

There have been some strategies here.

Mr. PEPPER. Excuse me, they also need credit from an unfair competitor, I mean protection, they need protection?

Dr. Y. That is correct. These practices are unfair to everyone concerned.

Let me tell you about my experience with this, members of the committee. Basically, what I had been exposed to on three different occasions, three different manufacturers in the past 2 years is essentially a bundling or linking of equipment with the use of intraocular lenses.

The idea being that you would get free, not really free, you understand, it is going to billed to Medicare as part of the costs of the intraocular device you are using, pieces of equipment, expensive pieces of equipment, you understand, and capital outlays up to $90,000 or more are what we are talking about.

Sometimes they will put these discounts on the invoices of the intraocular lenses, sometimes not. But the mechanism is not there in the medicare payment system always to pass these discounts through to the patient and Medicare. Some simple changes to see to it that those discounts get appropriately passed through could be implemented. Because I and others have been troubled by these actions by a few companies, we are hoping you will pursue proper remedies to bring an end to these abuses.

I was actually so horrified that some of these things would actually be going on, I had some recordings made of actual conversations presented to me by manufacturers' representatives for these things, and with your permission, I would like to play some excerpts. We have taken the names of the individuals and the companies off but the full tapes have been made available to your staff. I would like to have you listen to those excerpts now.

Mr. **Pepper**. We will be pleased to hear that.

[The tape was played and a transcript of the tape follows:]

(The following are excerpts of conversations between sales representatives of a major cataract lens production company and an ophthalmologist. These conversations occurred in April and May of 1985. This segment reveals enticements for the doctor to use the company's products.)

Salesman. What we do . . . is we establish a competitive price.

Doctor. Yeah.

Salesman. And we take a portion of that price, take a portion of that . . . and use, give it back to you as purchase credits . . . We have a video system right now, I don't know if you've got a video camera on your scope or not, it's a hell of a system . . . The camera alone usually sells for $8495. Right now the camera's on for $6,995. You can get a VCR, a monitor and a stand that it all fits on for $8,495. So in essence you're getting about $1,500 worth of video equipment at no charge.

Doctor. Uh huh.

Salesman. That's going to be on a limited time basis.

(This May 1985 conversation lays out the purchase credits available to this doctor over a three-year period, calculated from his use of products and volume of surgery in the past. The salesman assures the doctor that government authorities approve of this arrangement.)

Salesman. What we've done is we've projected out what you would earn over the next three years from us in purchase credits by simply using our products . . . If you chose to exercise all your credits today, you would have $95,000 . . . You know, what I'm telling you is that you could get your (brand name omitted) laser—we've covered the interest charge—and you could get all that with no cash outlay to us.

Doctor. You'd cover the interest charges?

Salesman. Oh yeah.

Doctor. With the additional discount . . .

Salesman. That's right

Doctor. . . . available. . . . And you say that this has been reviewed by the lens society—you talking about the American Intraocular Implant Society or implant society?

Salesman Right. HCFA . . .

Doctor. Health Care Financing Administration . . . Medicare and Medicaid looked at it?

Salesman. Yeah . . . There isn't any other company today that has gotten all the endorsement we have. And I think one of the reasons that we get it . . . our only game that we play is ophthalmology. If we screw it up, we're in trouble, you know, you're in trouble—it's something that I don't think either one of us wants to be a part of.

Doctor. That's right. You got to have the bases tagged on it, I'm sure. You're right . . . and that's our concern of course about it. And got to get it right . . . fix it the way my accountants want it and everything else . . . Okay, you say you can get investment tax credit if you get the equipment up front . . .

Salesman. Yep.

Doctor. . . . entitled to it, right?

Salesman. Yep.

Doctor. And depreciation on it?

Salesman. Yep.

(Finally, we learn that any savings the doctor enjoys need not be passed on to Medicare.)

Salesman. What you do is, you take your—let's say it comes to three and a quarter—all of a sudden you put $490 customary charge you know, for handling. As long as that's what they're reimbursing at, you wouldn't have any problems. See, actually, because of the reimbursement scheme we have set up for you, this program is even more ideal for you than it is for other parts of the country, because they've already got that price established. And they recognize that as the customary charge on IOLs. So you're in good shape there.

Dr. Y. As you can see, that is a very well rehearsed, sophisticated effort at marketing, and it is a credit to the ophthalmologists in this Nation, that they don't fall for these things very often.

There are some things, however, that you in Congress can do to minimize these things, and one of them is highlighting it at this hearing.

Another would be to make the reimbursement for intraocular lenses dependent upon an invoice system. If an invoice is required by Medicare, and credit discount appears on the invoice, it will go through to Medicare. That should be universally done, whether it is in the hospital, inpatient or hospital-based outpatient, ambulatory surgical center, or wherever it is done.

Then if there is something going on that shouldn't be going on, and it is not reflected in the invoice, the inspector general of HHS can take appropriate action when he finds out about those things, and I am sure he can investigate, and he has got information on those things.

Second, and this is a real important point, that you brought up, Chairman Pepper. I am referring to this business of two unequal payment systems for the hospital-based outpatient centers and the ambulatory surgical centers [ASC], which results in very grave underpayment to the outpatient surgery centers that are freestanding.

The freestanding ASC's have been reimbursed for cataract surgery at an arbitrarily low rate, and as a result, many of them, all the ones that I know of, lose money doing eye surgery.

They simply can't afford the equipment that is needed, and that causes these programs to be offered by and proferred by some of the manufacturers, because they know in order to do the surgery and use the intraocular lenses, and serve their patients, the ASC's need the equipment and they haven't got the funds to do it, since and they are not getting reimbursed appropriately from medicare for those capital expenditures.

At the same time, and inadvertently, I think, Congress really didn't intend this, but when they put the cap of the DRG's on the hospital inpatient, then they left open the hospital outpatient surgery to be billed at a cost-plus basis. Here is where you are talking about the hundreds of millions of dollars, and maybe you are right, a billion-plus a year, that can be saved if these can be brought down into proper alignment as I understand you are contemplating proposing.

What has happened as a result can be seen in the American Hospital Association's recent announcement of the biggest increase in cost margins, that is margin of operation, that they have had in 20 years came under the first year of the DRG's. This was accomplished in spite of decreased patient numbers, and decreased length of stay, by cutting back their costs—which was good—and increasing the amount of money they took in from their non-DRG services, that is, their outpatient services. Some of the charges for those hospital based outpatient services reimbursed under part B of Medicare have been fairly excessive—in some instances exceeding the costs for the same services on an in-patient basis—as you have evidence of. I think your committee report is very accurate in reflecting this.

If you make your proposal to equalize these two outpatient providers—at the same rate for the same outpatient surgery, regardless of where it is done, at some rate below the DRG, you will elevate what the free-standing centers get and decrease what hospitals receive. As a result the ASC will have the money they need to operate and get the equipment they need. As a result, the ASC and physicians won't have to be enticed into these kinds of illicit relationships with manufacturers to get the capital they need.

And at the same time, you will save the taxpayers money, help the public, and you really will protect the patients. I am for you, if you can get that done.

I think you are going to do it. Thank you.

[The prepared statement of Dr. Y follows:]

PREPARED STATEMENT OF DR. Y, OPHTHALMOLOGIST

Mr. Chairman and members of the committee, I wish to thank you for holding this hearing and listening to me on a matter which is of great concern to ethical health care providers and Medicare recipients. I am an ophthalmologist, an eye physician and surgeon, licensed as a medical doctor and currently in practice serving Medicare patients along with others. I personally perform cataract surgery including the implantation of intraocular lenses and own and work in a free standing ambulatory center as well as performing surgery in hospital inpatient and outpatient facilities.

I am also a licensor for patent rights to a medical company for the manufacture of an implantable ocular device for glaucoma and I am pleased that the firm I have a contract with has not and does not deal in any of the marketing strategies under review here.

Ethical doctors such as myself have been concerned for a long time over the marketing strategies of some of the companies that provide implantable eye devices, surgical supplies, and equipment. I can personally testify that on multiple occasions over the past two years, three independent firms have offered to provide me discounts on intraocular lenses in the form of equipment.

I am concerned at these marketing strategies because they are unfair to patients and unfair to the public.

Permit me to outline briefly the basic mechanism involved in these schemes that link equipment to the purchase of implantable devices. Essentially, in return for an agreement to purchase a large number of devices, the doctor is given some piece of equipment essentially free—the price having been included as a discount for the implantable device. Thus these marketing strategies permit and indeed encourage the provider to collect from Medicare an unauthorized payment for the equipment instead of passing through the appropriate discount as provided by law. As such, these schemes may represent a conspiracy on the part of the manufacturers so acting to commit Medicare fraud. Furthermore, in some instances marketing representatives have suggested to me that since title to the equipment so acquired will be transferred upon its delivery, I may claim investment tax credit and depreciation under the Internal Revenue Service codes. This encourages the doctor and providers to be claiming capital equipment tax deductions for items never purchased or separately invoiced and encourages expensing the cost off as an expensed item for the device.

As such, I am concerned that these strategies may also represent conspiracies to commit a fraudulent violation of the Internal Revenue codes.

One company engaged in these practices attempts to claim superiority of their scheme by listing a specific discount on the invoice for each intraocular lens. They then go on to state that since Medicare in most instances never sees the invoice, you, the doctor, may go ahead and accept the full Medicare payment. They even admit that they recognize that such schemes are illegal but quickly add that doing it their way makes it legal. It seems to those of us with conscience that if bank robbery is illegal, there can be no legal way to do it.

Because I have been troubled by the ethics of these sales inducements, I made several tape recordings of various sales presentations made to me in the past year. With your permission, Mr. Chairman, I would like to play an abbreviated version of one of these tapes. Names of salesmen and the manufacturer have been deleted, but I have made the full tapes available to your staff.

As you can tell from this tape, it is a well rehearsed, sophisticated effort to convince me that I can get something for nothing.

I am concerned as are the vast number of doctors at these strategies because they are unfair; unfair to the patients and unfair to the public that pays the Medicare bills.

Unfair to the patients because through such devious practices the patients welfare may be secondary when it comes to decisions of which implantable device will be used. Instead of only considering the very best implant for a particular patient we now have a system that permits the decision to be made on the basis of what free equipment can be provided.

And these schemes are unfair to the public by abusing the Medicare program and depriving discounts to be passed through as savings as required by the law.

Recognizing that a problem does indeed exist leads me to suggest a two-pronged solution, both parts of which are, in my considered opinion, needed to stop these marketing practices.

Firstly, reimbursement by Medicare for all implantable devices should be made on an invoice cost plus a reasonable fixed stocking and handling charge by the provider, regardless of whether it is hospital or nonhospital, inpatient or outpatient. If the Health Care Financing Administration would simply request an invoice copy with each request for payment for a device then posted discount would be passed on to them. Furthermore, and more significantly, they would then become aware of the specific manufacturer in each case. If the Inspector General of Health and Human Services had evidence that a given manufacturer and/or provider were engaged in fraudulent discount practices and such discounts were not reflected properly on the invoice, he and HCFA could exercise the option of refusing payments until such parties had complied and satisfied the agency. I believe such a mechanism change is possible by altering agency policy without legislative action.

Secondly, and equally important, there should be a stop to the discriminatory payment system that results in vastly unequal payments to ambulatory surgery centers versus hospital outpatient surgery departments for the same services. Ambulatory surgery centers have been encouraged to develop as mandated by Congress and have been widely recognized as providing highest quality medical care and great savings to patients and the Medicare system. Medicare reimbursement for procedures of such centers are at fixed rates which are widely and universally known to be below the cost of service. Virtually all free standing surgery centers, including my own, lose money on the Medicare schedule. At the same time, hospital based outpatient surgical providers are reimbursed by Medicare under part B on a cost-plus basis. This results in the hospital being reimbursed many times more than ambulatory surgery centers for eye surgery. Given this unfair inequity in payment it is a small wonder that ambulatory surgical centers and doctors are looking for discounts as a means to provide capital for the equipment they need to provide the quality care for their patients. Under funding by Medicare for the basic facility threatens the survival of these highly efficient and cost-saving providers. By raising the Medicare reimbursement for eye surgery in such centers to appropriate levels and finding a means to keep such payment schedules current and at the same time setting the hospital outpatient reimbursements to the same level should restore fairness to the system and vastly diminish the drive to use discounts on implantable devices for equipment funding. Additionally, such a measure would save Medicare many hundreds of millions of dollars by terminating excessive payments to hospitals. One estimate of the impact of such reform on the budget indicates an annual savings of up to one billion dollars from eye surgery alone from the Medicare budget, without the loss of any services to patients or public or any jobs. Certainly this is a measure that deserves strong bipartisan support in Congress.

I thank you for the invitation to testify and your willingness to listen. I remain at your service to answer your questions to the best of my ability.

Mr. **Pepper**. Thank you particularly, Doctor.

Did you hear the substance of the recommendations that I mentioned a while ago? Would those generally be in the right direction?

Dr. Y. I think you are on the right track. If you implement those things, you are talking, as I understand it, about a set rate for both hospitals and freestanding ASC's that is equal and then for a period of time, perform a study, to see if there is any reason that there should be differences in payment.

Nobody has those figures today, I believe.

Mr. **Pepper**. What savings in costs should be possible because of improvements in techniques and the like? Instead of patients having to stay in the hospital three days and a doctor having to take three hours to perform an operation, the patient can stay a relatively short time, and the doctor can perform the operation in 20 minutes. There should be some cost improvement, just like ordinarily in our manufacturing process, when we have mass production, we can reduce the cost of the product.

Dr. Y. I think you are right, you can have considerable savings in the reduction of the care when outpatient service substitutes for expensive inpatient care with the additional postoperative care in the hospital.

You are talking about big dollars there, and that difference probably is going to amount—by your committee's estimate—to maybe up to $1 billion a year.

You know, you talk about doing cataract operation in 20 minutes. It takes me longer than that, because it is a very delicate operation, and I am not sure that you can pay for things by the minutes that things get done, you know.

The French discovered an interesting thing back many, many centuries ago. They taxed buildings by the number of windows in them. You know what happened? They went on for 100 years, and they built buildings with no windows.

If you pay for operations by how long it takes, pretty soon they are going to take 5 or 6 hours to do some things.

You have to look at the level of skill involved and all of these things, and you are not going to get a tremendous savings, but I must confess in a delicate operation, to me an awful lot goes into it, and it is more like an hour for me to do one, and I think that especially as we get into these finer techniques, working under the microscope, you are not saving a great deal of money in that regard, but where you save the money is in that post-operative care, if the patient can be rehabilitated by these modern methods, recovering at home, in their own environment, where they are comfortable, much can be saved. Not all patients can do that, for surely there are patients that need the hospitalization because they are sicker, or maybe blind in the other eye or have some other reason for hospitalization.

And so, there are reasons for hospitalization for cataract surgery, and that is appropriate.

In these cases, the extra payment should be made, some reasonable amount, so the hospitals can function and provide that service.

But when you can perform the service on an outpatient, you should have some money over inpatient costs.

Mr. **Pepper**. Doctor, would you care to state whether you have been offered any inducement that you didn't deem ethical or fair by people involved in the manufacturing end of this product?

Dr. Y. Excuse me, Senator, I don't think I got the question right.

Mr. **Pepper**. Would you care to state whether you personally have been offered inducements other than your fair, regular fee by manufacturers who wanted you to use their product?

Dr. Y. As you heard from the tape, I have been offered essentially equipment bundling where certain expensive equipment has been offered to me.

I want no part of that, I should say.

Mr. **Pepper**. Would you say that the practice of a manufacturer offering such inducements to ophthalmologists exists on a fairly large scale?

Dr. Y. That is a difficult question for me to ascertain, but if it comes into my office, it probably goes a lot of places, but I don't have any accurate statistics on it. Your committee probably has gathered more accurate data, and perhaps the Inspector General has more accurate data.

I think, you know, it certainly goes on, and it doesn't really make too much difference whether it is terribly widespread or occasional, it needs to be stopped.

Mr. **Pepper**. What was the value of the equipment that they offered you, Doctor?

Dr. Y. They had a value on it of $95,000.

Mr. **Pepper**. $95,000? Quite a bit of money.

Dr. Y. That is a lot of money.

Mr. **Pepper**. Well, it is a regrettable thing that such practices prevail, and that, in an honorable profession, an effort is made to corrupt these doctors.

Dr. Y. The members of the profession have been aware of this, and done a commendable job of getting the information out. Our own professional societies all over have really communicated to the membership, and I think the vast majority of the ophthalmologists are aware these things should not be done, and don't do them.

We just need your help to change the system a little bit, and I think we can put an end to it.

Thank you very much.

Mr. **Pepper**. Doctor, one other thing, I would like both you and your able predecessor here to understand that this subcommittee would be very grateful to you or your professional organization for any suggestions or recommendations relative to legislation that you would think in the public interest. We would be glad to have it.

Dr. Y. I thank you, and I am sure you will get information from the professional organizations on that.

Mr. **Skelton**. Doctor, you played a couple of tapes to us of manufacturers' inducements which appears from listening to them not to be ethical, is that not correct?

Dr. Y. That is correct.

Mr. **Skelton**. One of them, in essence, offers you $1,500 worth of video equipment at no charge?

Dr. Y. Yes, they were actually offering more than that.

Mr. **Skelton**. A discount rate?

Dr. Y. That is right.

Mr. **Skelton**. Explain this $95,000 figure that the second salesman mentioned to you, would you, please?

Dr. Y. That refers to portions that were deleted out of the tape, but your committee has the full tape, but there was a sizable amount of equipment. This equipment is essential to perform these various procedures, and it is equipment that anybody that operates a surgery center or a clinic needs to buy, needs to get reimbursed for appropriately, and if they are reimbursed appropriately and the levels are brought up, we can have the moneys to do that.

Unfortunately, they are not always there, and so, the companies come in and say, if you use our intraocular lenses for 3 years, we will give you this equipment free and that will enable you to do service to the patient and them to get the product sold, and that is why they do it that way.

Mr. **Skelton**. That was a $95,000 boon to a doctor who would accept this?

Dr. Y. That is correct.

Mr. **Skelton**. Would you say that this is the attempt to get someone to do something wrong?

Dr. Y. That is my simple-minded way to view it. People ask me, is it illegal? I don't practice law, so I don't give legal opinions about things, but as one of these representatives said, he said, you know all these other companies do these things and everything they are doing is illegal, but we found a way to do it that is legal.

I sort of think, if it is not legal to rob a bank, then there isn't any legal way to do it.

Mr. **Skelton**. Yes.

You know, I am sure the IRS would be interested to know if some of these doctors have accepted this $95,000 worth of equipment for the use of these intraocular lenses. Do you think that would be a safe statement, sir?

Dr. Y. You said it. I am not again giving any legal opinions, but I think there is a serious question that some of these practices represent a sort of a conspiracy to induce someone to perhaps violate Internal Revenue Service codes.

Mr. **Skelton**. Doctor, switching the subject, and by the way, I want to commend you for appearing here today. This is not easy for you. Yours is a proud profession, one of the finest and the oldest, and for you to appear, you are doing not just your profession, but you are doing your country a great service, and I compliment you as well as the other doctor.

Doctor, on another subject, you were saying that the outpatient charges were being in essence overloaded because of the ceiling or the cap that has been put on the other charges.

How would you feel about a prospective payment system for outpatient charges?

Dr. Y. I think that is what you are going to go to, I think that is the right answer, setting an appropriate level, something a little less than the DRG for inpatient, because you are not going to be taking care of the patients in the hospital for three days and stopping this cost-plus arrangement.

Your committee is going to come up with that kind of thing. That is going to be where you straighten the system out and save medicare money which it needs, and you are going to save that money without causing anyone to go without the surgery they need.

You are not going to have anybody losing any jobs. You are just going to set the system straight. It is picking up the details where it sort of fell between the cracks when you did your last revision of these things.

Mr. **Skelton**. Doctor, again, I thank you so much.

Mr. **Pepper**. Mary Rose Oakar.

Ms. **Oakar**. Senator, thank you very much.

I would like to ask that my opening statement be placed in the record. I am sorry I wasn't able to be here at the very beginning.

[The prepared statement of Ms. Oakar follows:]

PREPARED STATEMENT OF REPRESENTATIVE MARY ROSE OAKAR

Thank you, Mr. Chairman, I want to commend you and your staff for this important hearing today on the waste and misuse of Medicare funds for cataract surgery. We all know that cataract surgery is the most frequently performed surgical procedure reimbursed under the Medicare Program, so this is an appropriate area in which to examine our reimbursement practices and the efficacy of our efforts to eliminate waste and abuse.

I was very surprised to read the subcommittee's findings on our reimbursement practices for cataract surgery under Medicare. It appears that Medicare will pay more than twice as much for the identical procedure performed on an outpatient basis than it will for inpatient surgery. Certainly, this practice deserves our careful scrutiny. If we are, indeed, paying up to $1.2 billion more than we need to for cataract surgery each year, we should proceed with constructive reforms to eliminate that waste and free up funds for better Medicare coverage or other financial improvements.

Chairman Pepper, I applaud your leadership in this area. Unlike the Reagan administration, whose only purpose in the last five years has been to try to slash Medicare benefits and hike the cost of care to seniors, you have worked tirelessly to find constructive ways to improve Medicare. I look forward to our hearing today, to learning how we might better provide the service of cataract surgery under Medicare, and to continued work with you to find real, helpful ways to improve the Medicare Program.

Ms. **Oakar**. Doctor, one quick question, and I read your testimony. Again, I want to thank you and applaud my chairman for uncovering this. Chairman Pepper is one of the great advocates for programs that relate to the elderly.

He doesn't want to see Medicare cut when it serves the elderly well, in terms of quality care, but he does want to see abuses stopped, and this is a contrast from what the administration is trying to do.

Let me just ask you if you know of any instances where other of your colleagues have been given the same types of offers that—you don't have to name names. Do you suppose or know of any other cases whereby your colleagues have been offered these deals as well?

Dr. Y. I have no personal knowledge of any individuals that have been offered various things, but I read what our professional society puts out, and it appears that this must be going on more than just in my instance.

Ms. **Oakar**. It is a pretty wholesale operation, you would say?

Dr. Y. I think it is national in scope.

Ms. **Oakar**. Well, it is interesting. Senator, I know you are going to make some suggestions for reform. We would be able to save taxpayers billions of dollars and prevent some unnecessary practices for the consumer as well, if we reformed the manner in which we reimburse cataract surgery, among other things, so your testimony is really important.

We know professionally, it must be difficult for you to come, and I will tell you, what you are doing is very, very important. Thank you so much.

Thank you, Senator.

Mr. **Pepper**. Thank you very much, Ms. Oakar. Ms. Oakar has been one of the leading advocates for the elderly since she became a Member of Congress, and she is one of the leading members of the House Select Committee on Aging.

Let me just emphasize the suggestion that Ms. Oakar left. As I said a while ago, Alzheimer's disease is the fourth largest killer in the United States today. Yet, it is not covered by Medicare, and we know family after family which has been made destitute trying to take care of a loved one who is victimized by Alzheimer's disease.

We just don't so far have enough money in Medicare to cover that disease.

The more money we can save and still not impair the quality of service of a medical nature to the elderly, the more illnesses we can help, and the more aid we can give to the elderly in meeting their health problems.

The elderly ordinarily have about three times as much illness, three times as much need for medical assistance, as young people.

The other day, a lady almost brought tears to my eyes. She was in her thirties, had three children, and she had a liver disease and had to have a transplant. She told me she had been to several hospitals that do that sort of thing.

They told her it would cost $150,000 in the hospital, and probably another $50,000 before the operation was completed. The lady said, "I have been able to raise from kind contributors $45,000, but they told me that if I don't have the operation within the next 6 or 9 months, I will be dead in the next 12 months."

She said, "What am I going to do?" So far, I don't think we are covering any transplants, are we? I don't believe any transplants are covered, and yet there are thousands of people all over America, including elderly people, of course, many of whom need these transplants to live.

I called Mr. Stockman who, at that time, was head of the OMB, and I said, "You know more about the Government than anybody I know. Is there any place in the Government of the United States where we can get any help for this lady who came to see me?"

He checked into it, and called me back and said, "I don't know of anything that is available under the United States' programs," so there are all kinds of illnesses that the elderly are suffering from today which are not covered by Medicare.

Today, the elderly are having to pay 20 percent of their gross income on the average for their medical care. That is in spite of the fact that we have Medicare. And that is exactly the same percentage of their own income they were paying in 1965, when Medicare was started.

We thought when we got Medicare that would, to a large degree, take care of the costs of medical care for the elderly, and of course, now they are having to pay back. When we try to save money, we are trying to provide some funds that will aid other people who need medical care.

Well, Doctor, thank you very much.

Ms. **Oakar**. Senator, will you yield?

There are many things that are not covered by Medicare. You and I have a bill that relates to prevention. We don't cover physicals for colon cancer, for example, or breast examinations, and the No. 1 killer for women, as we know now, in breast cancer. It is so backwards what we are doing, and here we allow this kind of ripoff to take place.

Mr. **Pepper**. It is estimated in this area, the savings might amount to $2 billion a year. Imagine how much help that would give to other ill people in America, if we could make it available to them.

Our next witness is Hon. Richard Kusserow, inspector general, U.S. Department of Health and Human Services.

You may proceed.

STATEMENT OF HON. RICHARD KUSSEROW

Mr. **Kusserow**. I am Richard Kusserow, inspector general for the Department of Health and Human Services, and with me is Barry Steeley of our staff. We would like to thank you for the opportunity to testify today on the findings of a recent audit and the preliminary findings of an inspection which focus on issues relating to Medicare reimbursement for cataract surgery. The draft report of our inspection will be prepared in the next few weeks.

I will summarize my statement and submit the full text for the record, if that is all right.

Mr. **Pepper**. Without objection, the statement will be received.

Mr. **Kusserow**. Historically, cataract surgery was performed in an inpatient hospital setting. Surgery took as long as 2 hours and usually was performed under general anesthesia. Hospital stays of 3 to 7 days were the rule. Within the last several years, technological advances in ophthalmic surgical procedures and anesthesia techniques have significantly changed the manner in which the surgery is performed. Today, most cataract surgery is performed in hospital outpatient departments, ambulatory surgical centers, and physician-owned clinics.

In the course of conducting a recent inspection, we interviewed dozens of Medicare beneficiaries who had cataract surgery. These persons expressed an overwhelming positive reaction to the results of their surgery. They also expressed a preference for outpatient surgery performed under local anesthesia. The shift toward outpatient surgery has also been aided by Medicare reimbursement and administrative changes. First, cataract procedures performed in an inpatient setting under the Medicare prospective payment system fall under Diagnosis Related Group 39.

Hospitals are paid between $1,200 and $1,500 under PPS for this procedure. The weighting for DRG-39 was determined using a data set which covered a period when IOL's were not used in the majority of cataract surgeries. In addition, many of the sophisticated diagnostic tests commonly used today in connection with this surgery were not available. These factors have made inpatient cataract surgery unprofitable for many hospitals. Second, many peer review organizations, PRO's, have discouraged the admission of patients for cataract surgery by requiring a pre-admission review of all such cases before authorizing hospital payment.

In stark contrast with our praise for the improvement in the quality of life for Medicare beneficiaries brought about by these advances in ophthalmic surgery is our condemnation of profiteers who are engaged in sophisticated schemes to defraud and abuse the Medicare Program and bilk the elderly out of millions of dollars through exorbitant profits on intraocular lens. Our staff have developed information involving cash payments, stock deals, free lenses, free equipment, free vacations, lavish gifts, and the laundering of Medicare Program and beneficiary funds through the Grand Cayman Islands. The circumstance that give rise to these ripoffs is the excessive Medicare payments for lenses. The Medicare Program pays for 80 percent to 85 percent of all cataract surgeries and IOL's in the United States.

The major manufacturers of these intraocular lenses include IOLAB, a subsidiary of Johnson & Johnson; CILCO, a Rorer Group Corp.; Intermedics; American Medical Optics, a subsidiary of American Hospital Supply; Precision-Cosmet, a subsidiary of Frigitronics; Optical Radiation Corp.; and Coopervision. We are not implying that these corporations are engaged in an organized effort to defraud the Medicare Program and its beneficiaries. For the most part, we have found that these schemes are the work of overly-aggressive salesmen who are responding to the pressures brought on by fierce competition within this high-profit industry. Most of these salesmen are on a commission basis and some are not even employees of the manufacturers themselves. Without the excessive Medicare payments for these lenses, these schemes could not survive.

We would like to show the members of the committee a typical IOL. It is made of a plastic material known as PMMA, and costs about $35 to manufacture. By the time you add in the salesman's commission and other marketing expenses, you come to a total cost of $100 to $150, depending on the manufacturer. It is then purchased by a hospital or an ophthalmologist typically for prices that range from $150 to $250. In most cases, this provider "marks up" the lens and bills medicare between $300 and $700. We are talking about the average amounts billed to Medicare. We have reviewed bills for less than $300, but we have also found some bills for significantly more than $700.

This problem is not Medicare's alone. If the lens is provided in a hospital outpatient or clinic setting, the Medicare beneficiary is responsible for 20 percent of the allowed amount. We have found instances in which the beneficiary's liability alone exceeded the provider's cost for the lens.

In the course of performing our inspection field work to date, we have documented an astonishing range of prices and charges for these lenses. As you can see by this chart, on attachment A of our formal submission of our testimony, hospitals pay between $175 and $400 for lenses. However, we have found that some large hospitals who use a competitive process for purchasing lenses are able to obtain them for under $150. We have found that these providers have billed and the Medicare Program has paid amounts ranging from $250 to $790.

The range of prices and charges is even more astonishing when an ophthalmologist purchases and bills for the lens. As you can see, the amounts paid by these physicians ranges from $0 to $425 per lens. We will explain this zero figure. We found a physician who receives his lenses free in exchange for allowing one of the manufacturers to use his name in marketing their lens.

This "designer lens" phenomenon is prevalent in this industry where image is everything. Manufacturers are eager to sign up the leading ophthalmologists to aid in their marketing activities. Recently, Optical Radiation Corp. and IOLAB have begun the marketing of lenses which have a built-in ultraviolet light blocker and also lenses which have a laser ridge which facilitate the performance of post-operative procedures. Neither of these features significantly increase manufacturing cost. The endorsement of a well-known ophthalmologist is considered important in the marketing strategies of these manufacturers.

To get back to the surgeon who received free lenses. We wouldn't be concerned if the Medicare Program had benefited from his relationship with the manufacturer. Unfortunately, he billed $500 for each of the 1,600 free lenses he used last year. That means he made $80,000 profit on the lenses alone; $64,000 was paid by Medicare; and $16,000 was charged to his patients. Including his surgical fees, this physician was paid over $1.3 million last year by the Medicare Program. Physicians generally bill Medicare between $375 and $580 for their lenses. Medicare pays anywhere between $144 and $400. The beneficiary has to pay an additional $36 to $180.

In order to put this amount in perspective, we have determined that these same lenses are commonly available in Europe for $76 to $127, in U.S. dollars, and in Canada for between $86 and $172 for hospitals and $186 to $265 for ophthalmologists. Since the Medicare Program is willing to pay 200 to 500 percent of the provider's cost for lenses, it is not surprising that abusive schemes are not uncommon. Based on a statistically valid sample of the cases reviewed, we estimate that Medicare paid ophthalmologists $6.5 million more than their costs for lenses last year.

Medicare beneficiaries were liable for another $2.8 million. We have also looked at lens costs when provided by hospitals in two States, New York and California. If the findings are supported in the States we are currently looking at, then the Medicare reimbursement for all lenses exceeds provider costs by more than $50 million. We are now looking at hospital costs and charges in the States of Pennsylvania, Florida, Texas, and Washington. We are working closely on this review with Dr. Carolyne Davis, the Administrator of the Health Care Financing Administration, and we will be sharing our findings and recommendations with HCFA before we finalize our report.

Our reimbursement problems relating to cataract surgery do not end with the reimbursement for lenses. We are equally concerned about the level of professional fees paid in connection with this surgery. When cataract surgery is performed, Medicare pays separate bills to the surgeon, anesthesiologist, and sometimes an assistant surgeon.

The chart I now have before me, attachment B, displays the range of fees which are reimbursed to these three professionals. The surgical fee billed to Medicare ranges from $1,200 to $3,000, and Medicare pays between $960 and $2,000. The Medicare payment is based on charges. This charge structure was established during the late seventies when cataract surgery with an IOL implant was an experimental procedure performed by only a handful of ophthalmologists. Today, nearly every ophthalmologist is skilled in techniques which have reduced surgical time from 2 hours to less than 30 minutes. It is difficult to draw conclusions about whether this surgical fee is too high. We would point out, however, that we encountered numerous ophthalmologists who were paid more than $1 million by Medicare in 1984. In fact, an eye clinic operated by a Florida surgeon performed over 5,000 cataract surgeries in 1984, and he received $6.4 million in reimbursement from Medicare. In the State of Texas alone, six ophthalmologists were paid over $1 million.

With your permission, we would also like to present to the committee a report to our office recently issued, entitled "Review of Medicare Payments for Assistant Surgeon Services During Cataract Surgery."

Our report issued June 7, 1985, concluded that although the ophthalmologists require assistance during cataract surgery, such assistance is frequently provided by a surgical technician and/or operating room nurse. We are recommending that the Health Care Financing Administration exclude the services of an assistant surgeon from medicare coverage for routine cataract surgery. We would, of course, recommend that HCFA continue to provide coverage for an assistant surgeon where special medical conditions exist. We have estimated that this change would save the Medicare Program between $150 million to $200 million over a 5-year period. HCFA agrees with us in concept, but disagrees how to reimburse this.

In our current inspection of cataract surgery, we have looked at the medicare reimbursement for the facility fee and the lens. We have a chart, see attachment C, that shows the vast differences in the Medicare payment amounts depending on whether the surgery is performed in the hospital as an inpatient, an outpatient, in a free-standing ambulatory surgical center, or in a private clinic. If surgery is performed on an inpatient, the hospital is usually reimbursed under DRG–39 and the reimbursement includes the lens. The Medicare reimbursement ranges from $1,200 to $1,500. In an ambulatory surgical center, Medicare pays a facility fee of between $485 and $553, and pays separately for the lens an amount ranging from $280 to $400. So, Medicare's total reimbursement, excluding professional fees, is between $765 and $953. In a private physician's office, the facility fee is not reimbursible, so the Medicare Program pays only for the lens itself.

Our concern is the reimbursement to hospitals when cataract surgery is performed as an outpatient. Hospitals are paid what are termed "reasonable costs." Medicare pays between $1,250 and

$2,790 to hospitals in this setting. We do not see how this amount can be considered reasonable. We find it hard to believe that Medicare pays hospitals more when cataract surgery is performed on an outpatient basis than an inpatient basis. I think all of us recognize that it is significantly less costly for hospitals to perform this procedure on an outpatient basis. In our final inspection report, our office will be recommending that we limit the reimbursement for outpatient cataract surgery to the lower of the amount paid to an ambulatory surgical center or the in-hospital DRG rate. It is estimated that if the hospitals were paid under this method, that Medicare would save in the neighborhood of $325 million per year.

The information we have presented indicates that the Medicare Program payments for a single cataract surgical procedure may be as little as $2,037 or as much as $6,940 depending on an array of factors, including the setting of the procedure, the ophthalmologist who performs the procedure, whether an assistant surgeon is used, and whether the lens is "marked up." We have documented an incredible range of charges to beneficiaries resulting from cataract surgery. In one instance, we are aware of the beneficiary is required to pay over $2,000 out-of-pocket for the surgeon and the anesthesiologist's fees. In addition, Medicare was billed almost $6,000 for the same cataract procedure.

We would also like to present for the record numerous advertisements showing that in areas where competition for patients is most keen, providers and ophthalmologists frequently waive the beneficiaries' liability resulting in cataract surgery at no cost to the Medicare beneficiary, which raises a whole subset of questions which should be examined. We point out these facts because we sympathize with the plight of Medicare beneficiaries who must thread their way through an almost incomprehensible quagmire of health care marketing gimmicks and illogical Medicare reimbursement policies to obtain the surgery which will restore their sight.

Before closing, we would like to comment on two additional issues. This spring, we testified before this committee on my need for expanded administrative sanction authorities to deal with the types of fraudulent and abusive schemes which we detailed in our testimony today.

We would like to personally thank each member of this committee and the House of Representatives as a whole for passing H.R. 1868, which provides our office with the additional authority we need to punish those persons who are engaged in defrauding or abusing our health care programs.

For the record, we would like to express our hope that the Senate will act expeditiously to pass similar legislation so that we may pursue our personal goal of stopping health care ripoffs and insuring that our scarce health care funds reach their intended beneficiaries, the aged and disadvantaged persons of this Nation.

A leading force in dealing with the problem of improper activities in cataract surgeries are with the professionals themselves. Specifically, we have worked very closely with the American Academy of Ophthalmology, who have assisted us and guided us in directing us to areas where we need additional examination, to ferret out individuals engaging in unethical or illegal types of arrangements with manufacturers, and for that, we are really grateful and particularly so because it has become apparent that this is a new and burgeoning problem, and in the eighties, only 25 percent of the cataract surgery procedures involved in IOL, and today we are approaching 90 percent, so it is a very dynamic change in medical practice, and it is a new problem for us.

And it is with the aid of the kinds of the health professionals we have had testify here already today that we will be able to get on top of this problem, and we stand ready to answer any questions you may have at this time.

[The prepared statement of Mr. Kusserow follows:]

PREPARED STATEMENT OF RICHARD P. KUSSEROW, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

GOOD MORNING MR. CHAIRMAN, I AM RICHARD P. KUSSEROW, INSPECTOR GENERAL (IG) OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. I WOULD LIKE TO THANK YOU FOR THE OPPORTUNITY TO TESTIFY TODAY ON THE FINDINGS OF A RECENT AUDIT AND THE PRELIMINARY FINDINGS OF AN INSPECTION WHICH FOCUS ON ISSUES RELATING TO MEDICARE REIMBURSEMENT FOR CATARACT SURGERY. THE DRAFT REPORT OF OUR INSPECTION WILL BE PREPARED IN THE NEXT FEW WEEKS.

OVER THE PAST 7 YEARS, WE HAVE WITNESSED ONE OF THE GREATEST ADVANCES IN THE HISTORY OF OPHTHALMIC SURGERY WITH THE EXPANDED USE OF INTRAOCULAR LENSES (IOL), IMPLANTED IN THE EYE TO REPLACE THE NATURAL LENS WHICH IS REMOVED AS A RESULT OF CATARACT SURGERY. EVERYONE RECOGNIZES THAT THE IMPLANTATION OF AN IOL IS A DRAMATIC IMPROVEMENT OVER THE USE OF CATARACT GLASSES WHICH RESTRICTED A PERSON'S PERIPHERAL VISION; OR THE EXTERNAL CONTACT LENSES WHICH ARE DIFFICULT FOR THE ELDERLY TO HANDLE. AT THE SAME TIME, WE MUST BE CONCERNED WITH THE EXPLOSION IN MEDICARE PAYMENTS FOR CATARACT SURGERY AND WITH THE WIDESPREAD ALLEGATIONS OF KICKBACKS AND FRAUDULENT SCHEMES INVOLVING THE MARKETING OF INTRAOCULAR LENS.

CATARACT SURGERY IS THE MOST FREQUENT PROCEDURE PERFORMED ON THE MEDICARE POPULATION IN THE UNITED STATES TODAY. THIS YEAR BETWEEN 850,000 AND 900,000 AMERICANS WILL HAVE A CATARACT REMOVED. TODAY, OVER 90 PERCENT OF ALL CATARACT SURGERY INVOLVES THE IMPLANTATION OF AN INTRAOCULAR LENS. THIS PERCENTAGE IS STAGGERING WHEN YOU CONSIDER THAT AS RECENTLY AS 1980, ONLY 25 PERCENT OF ALL CATARACT OPERATIONS INVOLVED THE IMPLANTATION OF AN IOL.

HISTORICALLY, CATARACT SURGERY WAS PERFORMED IN AN INPATIENT HOSPITAL SETTING. SURGERY TOOK AS LONG AS 2 HOURS AND USUALLY WAS PERFORMED UNDER GENERAL ANESTHESIA. HOSPITAL STAYS OF 3-7 DAYS WERE THE RULE.

WITHIN THE LAST SEVERAL YEARS, TECHNOLOGICAL ADVANCES IN OPHTHALMIC SURGICAL PROCEDURES AND ANESTHESIA TECHNIQUES HAVE SIGNIFICANTLY CHANGED THE MANNER IN WHICH THE SURGERY IS PERFORMED. TODAY, MOST CATARACT SURGERY IS PERFORMED IN HOSPITAL OUTPATIENT DEPARTMENTS, AMBULATORY SURGICAL CENTERS, AND PHYSICIAN OWNED CLINICS. IN THE COURSE OF CONDUCTING A RECENT INSPECTION, WE INTERVIEWED DOZENS OF MEDICARE BENEFICIARIES WHO HAD CATARACT SURGERY. THESE PERSONS EXPRESSED AN OVERWHELMING POSITIVE REACTION TO THE RESULTS OF THEIR SURGERY. THEY ALSO EXPRESSED A PREFERENCE FOR OUTPATIENT SURGERY PERFORMED UNDER LOCAL ANESTHESIA.

THE SHIFT TOWARD OUTPATIENT SURGERY HAS ALSO BEEN AIDED BY MEDICARE REIMBURSEMENT AND ADMINISTRATIVE CHANGES. FIRST, CATARACT PROCEDURES PERFORMED IN AN INPATIENT SETTING UNDER THE MEDICARE PROSPECTIVE PAYMENT SYSTEM (PPS) FALL UNDER DIAGNOSIS RELATED GROUP (DRG)-39. HOSPITALS ARE PAID BETWEEN $1200 - $1500 UNDER PPS FOR THIS PROCEDURE. THE WEIGHTING FOR DRG-39 WAS DETERMINED USING A DATA SET WHICH COVERED A PERIOD WHEN IOLS WERE NOT USED IN THE MAJORITY OF CATARACT SURGERIES. IN ADDITION, MANY OF THE SOPHISTICATED DIAGNOSTIC TESTS COMMONLY USED TODAY IN CONNECTION WITH THIS SURGERY WERE NOT AVAILABLE. THESE FACTORS HAVE MADE INPATIENT CATARACT SURGERY UNPROFITABLE FOR MANY

HOSPITALS. SECONDLY, MANY PEER REVIEW ORGANIZATIONS (PROS) HAVE DISCOURAGED THE ADMISSION OF PATIENTS FOR CATARACT SURGERY BY REQUIRING A PRE-ADMISSION REVIEW OF ALL SUCH CASES BEFORE AUTHORIZING HOSPITAL PAYMENT.

IN STARK CONTRAST WITH OUR PRAISE FOR THE IMPROVEMENT IN THE QUALITY OF LIFE FOR MEDICARE BENEFICIARIES BROUGHT ABOUT BY THESE ADVANCES IN OPHTHALMIC SURGERY IS OUR CONDEMNATION OF PROFITEERS WHO ARE ENGAGED IN SOPHISTICATED SCHEMES TO DEFRAUD AND ABUSE THE MEDICARE PROGRAM AND BILK THE ELDERLY OUT OF MILLIONS OF DOLLARS THROUGH EXORBITANT PROFITS ON INTRAOCULAR LENS. OUR STAFF HAVE DEVELOPED INFORMATION INVOLVING CASH PAYMENTS, STOCK DEALS, FREE LENSES, FREE EQUIPMENT, FREE VACATIONS, LAVISH GIFTS, AND THE LAUNDERING OF MEDICARE PROGRAM AND BENEFICIARY FUNDS THROUGH THE GRAND CAYMAN ISLANDS.

THE CIRCUMSTANCE THAT GIVE RISE TO THESE RIPOFFS IS THE EXCESSIVE MEDICARE PAYMENTS FOR LENSES. THE MEDICARE PROGRAM PAYS FOR 80 PERCENT TO 85 PERCENT OF ALL CATARACT SURGERIES AND IOLS IN THE UNITED STATES. THE MAJOR MANUFACTURERS OF THESE INTRAOCULAR LENSES INCLUDE IOLAB, A SUBSIDIARY OF JOHNSON AND JOHNSON; CILCO, A RORER GROUP CORPORATION; INTERMEDICS; AMERICAN MEDICAL OPTICS, A SUBSIDIARY OF AMERICAN HOSPITAL SUPPLY; PRECISION-COSMET, A SUBSIDIARY OF FRIGITRONICS; OPTICAL RADIATION CORPORATION; AND COOPERVISION.

WE ARE NOT IMPLYING THAT THESE CORPORATIONS ARE ENGAGED IN AN ORGANIZED EFFORT TO DEFRAUD THE MEDICARE PROGRAM AND ITS BENEFICIARIES. FOR THE MOST PART, WE HAVE FOUND THAT THESE

SCHEMES ARE THE WORK OF OVERLY AGGRESSIVE SALESMEN WHO ARE RESPONDING TO THE PRESSURES BROUGHT ON BY FIERCE COMPETITION WITHIN THIS HIGH PROFIT INDUSTRY. MOST OF THESE SALESMEN ARE ON A COMMISSION BASIS AND SOME ARE NOT EVEN EMPLOYEES OF THE MANUFACTURERS THEMSELVES. WITHOUT THE EXCESSIVE MEDICARE PAYMENTS FOR THESE LENSES, THESE SCHEMES COULD NOT SURVIVE.

WE WOULD LIKE TO SHOW THE MEMBERS OF THE COMMITTEE A TYPICAL IOL (SHOW SAMPLE). IT IS MADE OF A PLASTIC MATERIAL KNOWN AS PMMA AND COSTS ABOUT $35 TO MANUFACTURE. BY THE TIME YOU ADD IN THE SALESMEN'S COMMISSION AND OTHER MARKETING EXPENSES, YOU COME TO A TOTAL COST OF $100 - $150 DEPENDING ON THE MANUFACTURER.

IT IS THEN PURCHASED BY A HOSPITAL OR AN OPHTHALMOLOGIST TYPICALLY FOR PRICES THAT RANGE FROM $150 - $250. IN MOST CASES, THIS PROVIDER "MARKS-UP" THE LENS AND BILLS MEDICARE BETWEEN $300 AND $700. WE ARE TALKING ABOUT THE AVERAGE AMOUNTS BILLED TO MEDICARE. WE HAVE REVIEWED BILLS FOR LESS THEN $300 BUT WE HAVE ALSO FOUND SOME BILLS FOR SIGNIFICANTLY MORE THAN $700.

THIS PROBLEM IS NOT MEDICARE'S ALONE. IF THE LENS IS PROVIDED IN A HOSPITAL OUTPATIENT OR CLINIC SETTING, THE MEDICARE BENEFICIARY IS RESPONSIBLE FOR 20 PERCENT OF THE ALLOWED AMOUNT. WE HAVE FOUND INSTANCES IN WHICH THE BENEFICIARIES' LIABILITY ALONE EXCEEDED THE PROVIDER'S COST FOR THE LENS.

IN THE COURSE OF PERFORMING OUR INSPECTION FIELD WORK TO DATE, WE HAVE DOCUMENTED AN ASTONISHING RANGE OF PRICES AND CHARGES FOR THESE LENSES. AS YOU CAN SEE BY THIS CHART (ATTACHMENT A), HOSPITALS PAY BETWEEN $175 AND $400 FOR LENSES. HOWEVER, WE HAVE FOUND THAT SOME LARGE HOSPITALS WHO USE A COMPETITIVE PROCESS FOR PURCHASING LENSES ARE ABLE TO OBTAIN THEM FOR UNDER $150. WE HAVE FOUND THAT THESE PROVIDERS BILLED AND THE MEDICARE PROGRAM HAS PAID AMOUNTS RANGING FROM $250 - $790.

THE RANGE OF PRICES AND CHARGES IS EVEN MORE ASTONISHING WHEN AN OPHTHALMOLOGIST PURCHASES AND BILLS FOR THE LENS. AS YOU CAN SEE, THE AMOUNTS PAID BY THESE PHYSICIANS RANGES FROM $0 TO $425 PER LENS. WE WILL EXPLAIN THIS ZERO FIGURE. WE FOUND A PHYSICIAN WHO RECEIVES HIS LENSES FREE IN EXCHANGE FOR ALLOWING ONE OF THE MANUFACTURERS TO USE HIS NAME IN MARKETING THEIR LENS.

THIS "DESIGNER LENS" PHENOMENON IS PREVALENT IN THIS INDUSTRY WHERE IMAGE IS EVERYTHING. MANUFACTURERS ARE EAGER TO SIGN UP THE LEADING OPHTHALMOLOGISTS TO AID IN THEIR MARKETING ACTIVITIES. RECENTLY, OPTICAL RADIATION CORPORATION AND IOLAB HAVE BEGUN THE MARKETING OF LENSES WHICH HAVE A BUILT-IN ULTRAVIOLET LIGHT BLOCKER AND ALSO LENSES WHICH HAVE A LASER RIDGE WHICH FACILITATE THE PERFORMANCE OF POST-OPERATIVE PROCEDURES. NEITHER OF THESE FEATURES SIGNIFICANTLY INCREASES MANUFACTURING COST. THE ENDORSEMENT OF A WELL KNOWN OPHTHALMOLOGIST IS CONSIDERED IMPORTANT IN THE MARKETING STRATEGIES OF THESE MANUFACTURERS.

TO GET BACK TO THE SURGEON WHO RECEIVED FREE LENSES. WE WOULDN'T BE CONCERNED IF THE MEDICARE PROGRAM HAD BENEFITED FROM HIS RELATIONSHIP WITH THE MANUFACTURER. UNFORTUNATELY, HE BILLED

$500 FOR EACH OF THE 1600 FREE LENSES HE USED LAST YEAR. THAT MEANS HE MADE $80,000 PROFIT ON THE LENSES ALONE; $64,000 WAS PAID BY MEDICARE; AND $16,000 WAS CHARGED TO HIS PATIENTS. INCLUDING HIS SURGICAL FEES, THIS PHYSICIAN WAS PAID OVER $1,300,000 LAST YEAR BY THE MEDICARE PROGRAM.

PHYSICIANS GENERALLY BILL MEDICARE BETWEEN $375 AND $580 FOR THEIR LENSES. MEDICARE PAYS ANYWHERE BETWEEN $144 AND $400. THE BENEFICIARY HAS TO PAY AN ADDITIONAL $36 TO $180.

IN ORDER TO PUT THIS AMOUNT IN PERSPECTIVE, WE HAVE DETERMINED THAT THESE SAME LENSES ARE COMMONLY AVAILABLE IN EUROPE FOR $76 - $127 (U.S. DOLLARS) AND IN CANADA FOR BETWEEN $86 - $172 FOR HOSPITALS AND $186 - $265 FOR OPHTHALMOLOGISTS.

SINCE THE MEDICARE PROGRAM IS WILLING TO PAY 200 PERCENT TO 500 PERCENT OF THE PROVIDER'S COST FOR LENSES, IT IS NOT SURPRISING THAT ABUSIVE SCHEMES ARE NOT UNCOMMON. BASED ON A STATISTICALLY VALID SAMPLE OF THE CASES REVIEWED, WE ESTIMATE THAT MEDICARE PAID OPHTHALMOLOGISTS $6.5 MILLION MORE THAN THEIR COSTS FOR LENSES LAST YEAR. MEDICARE BENEFICIARIES WERE LIABLE FOR ANOTHER $2.8 MILLION. WE HAVE ALSO LOOKED AT LENS COSTS WHEN PROVIDED BY HOSPITALS IN TWO STATES, NEW YORK AND CALIFORNIA. IF THE FINDINGS ARE SUPPORTED IN THE STATES WE ARE CURRENTLY LOOKING AT, THEN THE MEDICARE REIMBURSEMENT FOR ALL LENS EXCEEDS PROVIDER COSTS BY MORE THAN $50 MILLION. WE ARE NOW LOOKING AT HOSPITAL COSTS AND CHARGES IN THE STATES OF PENNSYLVANIA, FLORIDA, TEXAS, AND WASHINGTON. WE ARE WORKING CLOSELY ON THIS REVIEW WITH

DR. CAROLYN DAVIS THE ADMINISTRATOR OF THE HEALTH CARE FINANCING ADMINISTRATION (HCFA) AND WE WILL BE SHARING OUR FINDINGS AND RECOMMENDATIONS WITH HCFA BEFORE WE FINALIZE OUR REPORT.

WE BELIEVE IT IS CRITICALLY IMPORTANT FOR THE MEDICARE PROGRAM TO CHANGE ITS REIMBURSEMENT POLICIES SO THAT MEDICARE'S REIMBURSEMENT IS NOT BASED ON PROVIDER'S CHARGES BUT RATHER IS RELATED TO THE COST OF THESE LENS. WE ALSO BELIEVE IT IS NECESSARY TO PLACE AN OVERALL CAP ON THE AMOUNT PAID FOR LENSES TO PREVENT ABUSES INVOLVING INFLATED INVOICES PRICES. THIS APPROACH IS CONSISTENT WITH A RECOMMENDATION RECENTLY MADE BY THE GENERAL ACCOUNTING OFFICE RELATING TO EXTERNAL CATARACT LENSES IN ITS REPORT ENTITLED, OPPORTUNITIES TO REDUCE MEDICARE PAYMENTS FOR PROSTHETIC LENSES WHILE ENHANCING NATIONWIDE UNIFORMITY OF BENEFITS, JANUARY 10, 1985.

WE BELIEVE THAT A LEGISLATIVE CHANGE IS NECESSARY TO IMPLEMENT OUR RECOMMENDATIONS AND MY OFFICE IS AVAILABLE TO WORK WITH HCFA AND THE COMMITTEE TO STRUCTURE APPROPRIATE CHANGES. WE ARE CONVINCED THAT THE REDUCTION IN MEDICARE REIMBURSEMENT FOR LENSES WHICH WOULD RESULT FROM OUR RECOMMENDATIONS WILL MAKE RIPOFF SCHEMES UNPROFITABLE.

UNFORTUNATELY, OUR REIMBURSEMENT PROBLEMS RELATING TO CATARACT SURGERY DO NOT END WITH THE REIMBURSEMENT FOR LENSES. WE ARE EQUALLY CONCERNED ABOUT THE LEVEL OF PROFESSIONAL FEES PAID IN CONNECTION WITH THIS SURGERY. WHEN CATARACT SURGERY IS PERFORMED, MEDICARE PAYS SEPARATE BILLS TO THE SURGEON, ANESTHESIOLOGIST, AND SOMETIMES AN ASSISTANT SURGEON.

THE CHART I NOW HAVE BEFORE ME (ATTACHMENT B) DISPLAYS THE RANGE OF FEES WHICH ARE REIMBURSED TO THESE THREE PROFESSIONALS. THE SURGICAL FEE BILLED TO MEDICARE RANGE FROM $1200 TO $3000 AND MEDICARE PAYS BETWEEN $960 AND $2000. THE MEDICARE PAYMENT IS BASED ON CHARGES. THIS CHARGE STRUCTURE WAS ESTABLISHED DURING THE LATE SEVENTIES WHEN CATARACT SURGERY WITH AN IOL IMPLANT WAS AN EXPERIMENTAL PROCEDURE PERFORMED BY ONLY A HAND FULL OF OPHTHALMOLOGISTS. TODAY, NEARLY EVERY OPHTHALMOLOGIST IS SKILLED IN TECHNIQUES WHICH HAVE REDUCED SURGICAL TIME FROM 2 HOURS TO LESS THAN 30 MINUTES. IT IS DIFFICULT TO DRAW CONCLUSIONS ABOUT WHETHER THIS SURGICAL FEE IS TOO HIGH. WE WOULD POINT OUT, HOWEVER, THAT WE ENCOUNTERED NUMEROUS OPHTHALMOLOGISTS WHO WERE PAID MORE THAN $1 MILLION BY MEDICARE IN 1984 IN FACT, AN EYE CLINIC OPERATED BY A A FLORIDA SURGEON PERFORMED OVER 5,000 CATARACT SURGERIES IN 1984 AND HE RECEIVED $6.4 MILLION IN REIMBURSEMENT. IN THE STATE OF TEXAS ALONE, SIX OPHTHALMOLOGISTS WERE PAID OVER $1 MILLION.

THE REIMBURSEMENT HISTORY OF THIS PROCEDURE DEMONSTRATES THAT THE REASONABLE CHARGE REIMBURSEMENT METHODOLOGY IS NOT RESPONSIVE TO TECHNOLOGICAL CHANGES WHICH SIGNIFICANTLY REDUCE THE COMPLICATION RATES AND THE SURGICAL TIME NECESSARY TO PERFORM A PROCEDURE. WE BELIEVE IT IS TIME THAT CONSIDERATION BE GIVEN TO THE ESTABLISHMENT OF AN INDEPENDENT COMMISSION WHICH PERIODICALLY ASSESSES THE SKILLS AND TECHNIQUES ASSOCIATED WITH SURGICAL PROCEDURES AND MAKES RECOMMENDATIONS FOR MEDICARE REIMBURSEMENT MODIFICATIONS. THE FUNCTION OF THIS COMMITTEE WOULD BE SIMILAR TO THE FUNCTION THAT THE PROSPECTIVE PAYMENT ASSESSMENT

COMMISSION PERFORMS FOR THE HOSPITAL PAYMENT PROCESS. IT WOULD MAKE RECOMMENDATIONS FOR CHANGES IN REIMBURSEMENT BASED ON CHANGES IN THE SURGICAL PROCEDURE ITSELF.

WITH YOUR PERMISSION, WE WOULD ALSO LIKE TO PRESENT TO THE COMMITTEE A REPORT OUR OFFICE RECENTLY ISSUED ENTITLED REVIEW OF MEDICARE PAYMENTS FOR ASSISTANT SURGEON SERVICES DURING CATARACT SURGERY. OUR REPORT ISSUED JUNE 7, 1985, CONCLUDED THAT ALTHOUGH THE OPHTHALMOLOGISTS REQUIRE ASSISTANCE DURING CATARACT SURGERY, SUCH ASSISTANCE IS FREQUENTLY PROVIDED BY A SURGICAL TECHNICIAN AND/OR OPERATING ROOM NURSE.

THE FACT IS THAT THE PRIMARY REASON FOR AN ASSISTANT SURGEON IS TO FACILITATE HIGH VOLUME CATARACT SURGICAL PRACTICES. WE BELIEVE IT IS FAIR TO SAY THAT THE FLORIDA OPHTHALMOLOGIST WHO PERFORMS OVER 5,000 SURGERIES A YEAR NEEDS AN ASSISTANT. BUT WHY SHOULD MEDICARE PAY AN ADDITIONAL PROFESSIONAL FEE FOR SERVICES WHICH ARE NOT NECESSARY OR CAN BE PROVIDED BY NON-PHYSICIAN ASSISTANTS?

WE ARE RECOMMENDING THAT THE HEALTH CARE FINANCING ADMINISTRATION EXCLUDE THE SERVICES OF AN ASSISTANT SURGEON FROM MEDICARE COVERAGE FOR ROUTINE CATARACT SURGERY. WE WOULD, OF COURSE, RECOMMEND THAT HCFA CONTINUE TO PROVIDE COVERAGE FOR AN ASSISTANT SURGEON WHERE SPECIAL MEDICAL CONDITIONS EXIST. WE HAVE ESTIMATED THAT THIS CHANGE WOULD SAVE THE MEDICARE PROGRAM BETWEEN $150 MILLION TO $200 MILLION OVER A 5-YEAR PERIOD. WE UNDERSTAND THAT YOUR COMMITTEE IS CONSIDERING A LEGISLATIVE CHANGE WHICH WOULD IMPLEMENT THIS RECOMMENDATION AND WE ENTHUSIASTICALLY SUPPORT YOUR EFFORTS IN THAT REGARD.

IN OUR CURRENT INSPECTION OF CATARACT SURGERY, WE HAVE LOOKED AT THE MEDICARE REIMBURSEMENT FOR THE FACILITY FEE AND THE LENS. WE HAVE A CHART (SEE ATTACHMENT C) THAT SHOWS THE VAST DIFFERENCES IN THE MEDICARE PAYMENT AMOUNTS DEPENDING ON WHETHER THE SURGERY IS PERFORMED IN THE HOSPITAL AS AN INPATIENT, AN OUTPATIENT, IN A FREE STANDING AMBULATORY SURGICAL CENTER, OR IN A PRIVATE CLINIC.

IF SURGERY IS PERFORMED ON AN INPATIENT, THE HOSPITAL IS USUALLY REIMBURSED UNDER DRG-39 AND THE REIMBURSEMENT INCLUDES THE LENS. THE MEDICARE REIMBURSEMENT RANGES FROM $1200 - $1500.

IN AN AMBULATORY SURGICAL CENTER, MEDICARE PAYS A FACILITY FEE OF BETWEEN $485 - $553 AND PAYS SEPARATELY FOR THE LENS AN AMOUNT RANGING FROM $280 - $400. SO MEDICARE'S TOTAL REIMBURSEMENT (EXCLUDING PROFESSIONAL FEES) IS BETWEEN $765 - $953. IN A PRIVATE PHYSICIAN OFFICE, THE FACILITY FEE IS NOT REIMBURSABLE SO THE MEDICARE PROGRAM PAYS ONLY FOR THE LENS ITSELF.

OUR CONCERN IS THE REIMBURSEMENT TO HOSPITALS WHEN CATARACT SURGERY IS PERFORMED AS AN OUTPATIENT. HOSPITALS ARE PAID WHAT ARE TERMED "REASONABLE COSTS." MEDICARE PAYS BETWEEN $1250 AND $2790 TO HOSPITALS IN THIS SETTING. WE DO NOT SEE HOW THIS AMOUNT CAN BE CONSIDERED REASONABLE. WE FIND IT HARD TO BELIEVE THAT MEDICARE PAYS HOSPITALS MORE WHEN CATARACT SURGERY IS PERFORMED ON AN OUTPATIENT BASIS THAN AN INPATIENT BASIS. I THINK ALL OF US RECOGNIZE THAT IT IS SIGNIFICANTLY LESS COSTLY FOR HOSPITALS TO PERFORM THIS PROCEDURE ON AN OUTPATIENT BASIS.

IN OUR FINAL INSPECTION REPORT, OUR OFFICE WILL BE RECOMMENDING THAT WE LIMIT THE REIMBURSEMENT FOR OUTPATIENT CATARACT SURGERY TO THE LOWER OF THE AMOUNT PAID TO AN AMBULATORY SURGICAL CENTER OR THE IN HOSPITAL DRG RATE. IT IS ESTIMATED THAT IF THE HOSPITALS WERE PAID UNDER THIS METHOD THAT MEDICARE WOULD SAVE IN THE NEIGHBORHOOD OF $325 MILLION PER YEAR.

IN SUMMARY, THE INFORMATION WE HAVE PRESENTED INDICATES THAT THE MEDICARE PROGRAM PAYMENTS FOR A SINGLE CATARACT SURGICAL PROCEDURE MAY BE AS LITTLE AS $2037 OR AS MUCH AS $6940 DEPENDING ON AN ARRAY OF FACTORS INCLUDING THE SETTING OF THE PROCEDURE, THE OPHTHALMOLOGIST WHO PERFORMS THE PROCEDURE, WHETHER AN ASSISTANT SURGEON IS USED, AND WHETHER THE LENS IS "MARKED-UP."

WE HAVE DOCUMENTED AN INCREDIBLE RANGE OF CHARGES TO BENEFICIARIES RESULTING FROM CATARACT SURGERY. IN ONE INSTANCE WE ARE AWARE OF THE BENEFICIARY IS REQUIRED TO PAY OVER $2,000 OUT OF POCKET FOR THE SURGEON AND ANESTHESIOLOGIST'S FEES. IN ADDITION, MEDICARE WAS BILLED ALMOST $6,000 FOR THE SAME CATARACT PROCEDURE.

WE WOULD ALSO LIKE TO PRESENT FOR THE RECORD NUMEROUS ADVERTISEMENTS SHOWING THAT IN AREAS WHERE COMPETITION FOR PATIENTS IS MOST KEEN, PROVIDERS AND OPHTHALMOLOGISTS FREQUENTLY WAIVE THE BENEFICIARIES' LIABILITY RESULTING IN CATARACT SURGERY AT NO COST TO THE MEDICARE BENEFICIARY.

WE POINT OUT THESE FACTS BECAUSE WE SYMPATHIZE WITH THE PLIGHT OF MEDICARE BENEFICIARIES WHO MUST THREAD THEIR WAY THROUGH AN ALMOST INCOMPREHENSIBLE QUAGMIRE OF HEALTH CARE MARKETING

GIMMICKS AND ILLOGICAL MEDICARE REIMBURSEMENT POLICIES TO OBTAIN THE SURGERY WHICH WILL RESTORE THEIR SIGHT.

BEFORE CLOSING, WE WOULD LIKE TO COMMENT ON TWO ADDITIONAL ISSUES. THIS SPRING WE TESTIFIED BEFORE THIS COMMITTEE ON MY NEED FOR EXPANDED ADMINISTRATIVE SANCTION AUTHORITIES TO DEAL WITH THE TYPES OF FRAUDULENT AND ABUSIVE SCHEMES WHICH WE DETAILED IN OUR TESTIMONY TODAY. WE WOULD LIKE TO PERSONALLY THANK EACH MEMBER OF THIS COMMITTEE AND THE HOUSE OF REPRESENTATIVES AS A WHOLE FOR PASSING H.R. 1868 WHICH PROVIDES OUR OFFICE WITH THE AUTHORITY WE NEED TO PUNISH THOSE PERSONS WHO ARE ENGAGED IN DEFRAUDING OR ABUSING OUR HEALTH CARE PROGRAMS. FOR THE RECORD, WE WOULD LIKE TO EXPRESS OUR HOPE THAT THE SENATE WILL ACT EXPEDITIOUSLY TO PASS SIMILAR LEGISLATION SO THAT WE MAY PURSUE OUR PERSONAL GOAL OF STOPPING HEALTH CARE RIPOFFS AND INSURING THAT OUR SCARCE HEALTH CARE FUNDS REACH THEIR INTENDED BENEFICIARIES - THE AGED AND DISADVANTAGED PERSONS OF THIS NATION. FINALLY, WE WOULD LIKE TO EXPRESS OUR APPRECIATION FOR THE COOPERATION IN OUR ANTI-FRAUD EFFORTS WHICH WE HAVE RECEIVED FROM THE AMERICAN ACADEMY OF OPHTHALMOLOGY. SPECIFICALLY, WE ENDORSE THE STATEMENT MADE BY THE ACADEMY IN ITS JULY ISSUE OF ITS ARGUS NEWSLETTER WHICH STATES THAT OPHTHALMOLOGISTS WHO ARE ACCEPTING KICKBACKS SHOULD STOP THAT PRACTICE IMMEDIATELY.

THANK YOU.

A

INTRAOCULAR LENSES:
PROVIDER'S COST AND MEDICARE REIMBURSEMENT

SETTING	PROVIDER PAYS	PROVIDER BILLS	MEDICARE PAYS
HOSPITAL	$175–$400	$250–$790	$250–$790
AMBULATORY SURGICAL CENTER CLINIC OPHTHALMOLOGIST BILLED	$0–$425	$375–$580	$144–$408

B

PROFESSIONAL FEES RELATED TO CATARACT SURGERY

	RANGE OF FEES BILLED TO MEDICARE	REIMBURSED BY MEDICARE
OPHTHALMOLOGIST	$1,200–$3,000	$960–$2,000
ASSISTANT SURGEON	$440–$600	$192–$400
ANESTHESIOLOGIST	$200–$550	$120–$350
TOTAL PROFESSIONAL FEES	$1,840–$4,150	$1,272–$2,750

MEDICARE PAYMENT AMOUNTS
BY SETTING
(EXCLUDES PROFESSIONAL FEES)

	HOSPITAL IN-PATIENT	HOSPITAL OUT-PATIENT	CERTIFIED AMBULATORY SURGICAL CENTER	PHYSICIAN OWNED CLINIC
FACILITY FEE	$1,200-$1,500	$1,000-$2,000	$485-$553	- 0 -
LENS	Included In DRG	$250-$790	$280-$400	$144-$408
TOTAL	$1,200-$1,500	$1,250-$2,790	$765-$953	$144-$408

Mr. **Pepper**. Thank you very much, Mr. Inspector General.

May I ask you to give the best estimate you can of what savings you think should be made, or could reasonably be made, in these expenditures?

Mr. **Kusserow**. As I pointed out, a lot depends on how you make the cut. We do know we are paying far too much for the lenses themselves. It comes out to about $50 million more than the provider paid the manufacturer. We looked at that markup, the markup not from the manufacturer to the provider but from the provider to Medicare. We know there is a $50 million excess there. We suspect there is an inordinately large cushion between the manufacturer's costs and that which the provider pays.

The point of the assistant surgeon, which is becoming a problem in cataract surgery, looks like another $150 million to $200 million over a budget cycle we are paying out. In addition to that, depending upon the setting in which the surgery is performed, if we can put a reasonable cap on that, it seems fair conservatively we could save $325 million to Medicare. It looks like we are talking, in conservative terms, around half a billion dollars a year.

Mr. **Pepper**. Mr. Inspector General, you are familiar with the procedures of the Medicare Program. There are savings that could be made in Medicare expenditures which simply would benefit more health patients, would they not?

Mr. **Kusserow**. That is correct, Mr. Chairman. Any dollars we are able to recoup for the program goes into the trust funds that support the other health programs.

Mr. **Pepper**. That would permit Medicare to help more people who have illnesses that need care?

Mr. **Kusserow**. What we are finding is rather alarming. If there is any one dream we, as Americans, share more than any other dream, it is the sense of quality health care for ourselves, our children, and their children. What we are seeing is a risk, with the health care costs rising twice and thrice the general inflation rate. If we want to maintain the quality health care we are coming to expect, we will have to contain this escalation due to wasteful or abusive practices.

First and foremost, we want to protect the care we have. Also, if we do it effectively, then maybe we could expand the amount of our program's coverage without incurring additional costs.

Mr. **Pepper**. I saw a headline in the paper a day or two ago that said there had been a survey, and the survey revealed that—I don't remember what it related to, the elderly or people generally. Anyway, they appreciated health more than money or sex. That is pretty hard competition.

Mr. **Kusserow**. I think they tend to complement one another.

Mr. **Pepper**. Mr. Inspector General, is there any justification for larger payments being demanded for this operation on an outpatient basis in a hospital than for an inpatient basis in a hospital?

Mr. **Kusserow**. There doesn't seem to be any justification for that. I think we understand why that came about. As Congress tried to contain costs in Medicare, particularly in the hospital setting, by moving from a retrospective payment system to a prospective payment system, they capped and developed diagnostic-related groups with a range of payments that would be within each DRG.

Therefore, they sort of capped the overall costs in the hospital setting.

One of the effects of that has been to squeeze out of the hospital setting some additional costs in an outpatient capacity. What we are seeing—and there has been previous testimony already this morning—is that hospitals move to try to do more procedures in the uncapped part of Medicare, and that is in the outpatient area. If it were similarly capped, of course, the decision as to whether it should be an outpatient or inpatient would be strictly based upon what would be best for the patient.

Right now, we cannot be sure, because of the fact there are other inducements, other concerns on the part of the hospital, as to in which setting the surgery should take place.

Mr. PEPPER. What information do you have as to the approximate fair cost of this IOL to the manufacturer?

Mr. KUSSEROW. I don't know what a fair cost would be. I know what an unfair cost is. I think what we are seeing is an unfair cost. What we really need to do is look at and see what is appropriate profit.

We need two tiers. One is, what is the fair price to the manufacturer, the cost of the item in the manufacturer's cost. Second, what kind of markup should take place after the provider has purchased a lens. Just how much of value has been added by the provider once they have purchased the lens that should be charged to Medicare. I think in that arena is where we have the most severe problem.

We know there are certain costs associated with the manufacturer of the item. We know there are a lot of costs in development. The question is: What does the provider add that would rate doubling the cost that they paid for it? I think that that is the area of most severe abuse.

Also, what we have found, Mr. Chairman, is that—and one of the reasons we got into this—is, 2 years ago, we completed studies dealing with other areas of rising technology in the medical arena. That is with pacemaker implantation. We found something remarkably similar to what we are finding here. The tremendous markup from the manufacturers to the provider allowed for companies, manufacturers' representatives, or individuals acting on their own, to offer all kinds of added inducements to the provider to use their particular product.

The concern raised there is almost a replay of what we are hearing today. That is, are there inducements sufficient that would cause a provider to choose a product not on what is best for the patient but based upon what kind of inducements they get or what kind of kickbacks they get under the table?

Even more importantly than that, and even more of concern to all of us, is: Could a physician be influenced by these inducements to have surgery when it is not appropriate? Because for the population we are talking about, the Medicare population, any surgery is serious surgery. It is a risky matter. To put these people through that kind of added torment when it is unnecessary would be unconscionable.

Mr. **Pepper**. Mr. Inspector General, is there generally an additional charge to the patient beyond what Medicare pays for this operation and the IOL?

Mr. **Kusserow**. That is correct, Mr. Chairman. The patient picks up 20 percent of the cost of that lens when it is performed in an outpatient setting. Therefore, that adds on. The burden is not just to Medicare alone or to the trust funds to which that individual has contributed over their work life.

But, in addition to that is what you pointed out. That is one of the reasons why costs to the elderly for their health continue at a high, even though we are spending upwards to $100 billion in Medicare to protect their health. That is because a lot of the costs are passed to them.

Mr. **Pepper**. Is it not possible that since one-sixth of the people over 65 years of age, in spite of Social Security, have income below the poverty level, that these high costs may prevent—if there is a requirement that the patient pay an additional sum—may prevent some elderly people from having the benefit of this operation?

Mr. **Kusserow**. I think in this case what is startling is that the beneficiary may be paying actually what the manufacturer's cost was in the first place. There is no reason to suppose why they should be paying that cost.

Why isn't the cost sufficient that we are paying on the lens? Why do they not have to pass that burden on? There is no reason we have to pass that burden on at the present level even under current policies and procedures. There is no reason why we have to have that much of a cost passed on.

The concern also is on the program side. That is a policy question, certainly outside of my domain to question. I am on the side of the angels. I am against fraud, waste and abuse, and want to promote economy and efficiency. Whatever the Congress enacts, I want to see it is to meet the intent of the Congress.

There is a policy issue that having some sharing of the cost by the beneficiary will prevent an abuse on that side. That is a tendency not to have unnecessary surgeries, unnecessary medical services, because of the fact that something comes out of their own pocket. That is a policy call that is between the administration and the Congress.

Mr. **Pepper**. It would seem only reasonable, would it not, that people who have a proper sense of moral responsibility, and who are able to enable their fellow mankind, fellow citizens, to avoid blindness and be able to enjoy the blessing of sight. I'd think they would be proud they are able to make that contribution to them and still get a fair and reasonable profit for it without exploiting those people who are dependent upon their service, for the restoration of their sight.

Mr. **Kusserow**. The vast majority of the professionals are, in fact, adhering to their ethical oath and behaving that way. What is reprehensible is that there are individuals that choose not to do that. That is one of the reasons why, in my opening comments, I allude to the fact how grateful we were in the Inspector General's Office that the House of Representatives took the lead to pass legislation that would lead to a more effective policing of the system, not only for people that are committing fraud against the Medicare and Medicaid Programs, but for individuals that are engaging in abusive practices or abuse of patients in those programs, and allows us to be able to sanction them severely both in terms of monetary sanctions but also in terms of excluding them from participating in our programs, and also to take other sanctions that could lead to their losing their licenses.

It is unfortunate that the few cause so much problems for the many. For these few, as far as I am concerned—we have to have the tools to ferret them out and to bring them to the bar of justice.

Most of what we have been talking about has nothing to do with ethics. It has to do with the law. These people that engage in kickback arrangements, as far as I am concerned, not only should we relieve them of the responsibility of providing services, surgical services to our beneficiaries, we should relieve them of the responsibility of being an active member of free society and incarcerate them in the Federal penitentiary.

Mr. **Pepper**. One other question, General: Has your investigation revealed any instances in which unnecessary operations of this character have been performed?

Mr. **Kusserow**. We are a little early on that. What we are beginning to find—again, this is because of the dynamics—most of what we have heard this morning shows the instances described as to inducements being provided by manufacturers' representatives has been in the last couple of years. That is a factor of the tremendously fast advancement of this technology.

But what we are finding is the same disturbing patterns we found with pacemakers. That is, it looks exactly like that. It looks very much like there are inducements. It is very difficult to go into a surgeon's mind and make a determination as to what they were thinking. You can't help but wonder whether a surgeon who has become very dependent upon some sort of a financial inducement, whether when they get a little cash-short that they may not shade their professional judgment as to not only the device that they use, but also whether, in fact, it should be used. That pattern is beginning to emerge. We have certainly anecdotal information to indicate it is happening.

What is more disturbing is, it may be representative of something that is very much larger, looming under the surface.

Mr. **Pepper**. Ms. Oakar.

Ms. **Oakar**. Thank you, Mr. Chairman.

Just quickly, Mr. Kusserow, can you tell the committee if HCFA has given you data related to the cost of outpatient surgery of this kind?

Mr. **Kusserow**. Yes, of course.

Ms. **Oakar**. So, you do have that data?

Mr. **Kusserow**. One of the blessings of being an independent Inspector General is there is no data in the department that is off limits to me.

Ms. **Oakar**. So, you have the data for both outpatient and inpatient?

Mr. **Kusserow**. That is correct.

We have been working closely with HCFA. They are disturbed by the trends, also. The concern we have is, it was unforeseen two things would go hand in hand to result in such a radical shift in the locality of the surgery, the cataract surgery. One is, prospective payment would immediately go in tandem with the rising technology, becoming a very routine procedure to implant an IOL in an outpatient setting.

The end result has been a tremendous shift from an inpatient setting in the hospital to an outpatient. Both because that is—in many cases, the more appropriate setting for the surgery—but also because it is an uncapped area of Medicare.

Ms. OAKAR. The Senator hit on the point that this is not only a burden to the Medicare area of the trust fund, but also the senior citizens do pay 20 percent.

Mr. KUSSEROW. That is correct.

Ms. OAKAR. What would be a better deal for them—to get an outpatient kind of surgery or to have the hospital——

Mr. KUSSEROW. First and foremost, what is best for the beneficiary is what is best for them medically. You cannot make a rule saying that all surgeries can be performed in an outpatient setting or an ambulatory surgical center, because there may be other complicating factors that would warrant——

Ms. OAKAR. Let me tell you what concerns me a little bit. I hope we do not—you see, some of us are of the belief that the Medicare area is very biased toward the highest type of expenses, even though the fact—even though the fact is that, in this case, it seems to be more expensive for an outpatient type of situation. But, in general, Medicare encourages people to stay in the hospital.

We just had some regulations put out by the Secretary of HHS that will limit reimbursement for home health care, which to me does not make too much sense; but then, I am not Secretary of HHS.

We all know that the emphasis traditionally in Medicare is on more expensive health care, not necessarily what is needed. That is doctors' fees and hospital stays. So, I guess what I am asking you, beyond the medical question—which was kind of understood on my part—is, what would be cheaper for the older person? Even with these erratic high costs of outpatient care, what would be cheaper—to have the surgery and stay a couple of days in the hospital, or to have the outpatient kind of care—if everything was equal?

Mr. KUSSEROW. If everything was equal, the least advantageous setting for them would be the outpatient surgery. It would be better for either having the surgery in an ambulatory surgical center or in a hospital, than in an outpatient capacity.

Again, one of the—as you were pointing out, one of the very complicating aspects of health care policy is trying to make rules that govern a lot of different situations. The point you made is that it would seem that it would be cheaper to have that kind of surgery in an outpatient setting than in an inpatient setting in the hospital. Yet, we are finding that is not the case; it is more expensive to have the outpatient.

Ms. OAKAR. It is more expensive because people are ripping off the system. I don't mean the consumers, but those manufacturers and all those incentives they have been giving, unethical incentives, to doctors, et cetera.

Mr. KUSSEROW. Only one of the elements in the cost is the lens. There is also the cost of the surgical procedure itself. The aggregate amount of all of the elements, the cost of the surgery, and the setting, and also the lens, is that it is more expensive in an outpatient capacity than it is in an inpatient capacity, which would, on the face of it, seem to defy logic.

As to how much of that is a result of waste or abuse or fraud, that is very difficult to determine.

Ms. **Oakar**. That is why I asked you the question about data which you said you had access to.

But in a letter to Chairman Pepper, HCFA has indicated that—it says, quoting from the letter, with the permission of the chairman:

> Medicare information by procedure for cataract surgery is currently available for inpatient hospital care only. Information by procedure for physician services is not yet available. Data on procedures for outpatient hospital services are not collected.

So, you must know something we don't know. When I asked you the question, you indicated you have all this data.

Mr. **Kusserow**. I have all their data.

Ms. **Oakar**. They say they don't collect it. The point is, you don't have that data, do you?

Mr. **Kusserow**. The thing is, in addition to having benefit of HCFA data, I also generate my own data from my own studies. We are conducting our own audits and inspections in this area that we will be sharing with HCFA that will allow them to make better decisions as to health care policies. I have in my hands more information, at this point, than HCFA because of the original work we are doing.

Ms. **Oakar**. I see. I think the key is to give HCFA that data and to pass along your data to the Chairman. We think that is a key element in understanding the whole issue.

Mr. **Kusserow**. We shall do both.

Ms. **Oakar**. Thank you very much.

Mr. **Pepper**. Gentlemen, I want to thank you on behalf of our committee and express our appreciation that somebody with your ability and dedication is trying to protect the public interest.

Mr. **Kusserow**. Thank you, Mr. Chairman.

Mr. **Pepper**. Thank you.

We now move to panel two, the providers' response. First, we have the following witnesses: Mr. Gordon Smith, member of the board of directors, Association of Eye and Ear Hospitals, and executive director, The Eye Foundation, Birmingham, AL; Dr. John Gilmore, president of the American Intraocular Lens Implant Society, accompanied by Mr. David Karcher, executive director of AIOIS, Washington, DC; Dr. Douglas Williamson, president, accompanied by David McIntyre, secretary-treasurer, Outpatient Ophthalmic Surgery Society, Venice, FL; Dr. James Aquavella of Rochester, NY, associate secretary for health plans, American Academy of Ophthalmology; and Dr. Jerome Bettman, Woodside, CA, Chairman, Ethics Committee, American Academy of Ophthalmology.

PANEL TWO—THE PROVIDERS' RESPONSE: CONSISTING OF GORDON SMITH, MEMBER, BOARD OF DIRECTORS, ASSOCIATION OF EYE & EAR HOSPITALS, AND EXECUTIVE DIRECTOR, THE EYE FOUNDATION, BIRMINGHAM, AL; JOHN GILMORE, M.D., PRESIDENT, AMERICAN INTRA-OCULAR IMPLANT SOCIETY, ACCOMPANIED BY DAVID KARCHER, EXECUTIVE DIRECTOR, AMERICAN INTRA-OCULAR IMPLANT SOCIETY, WASHINGTON, DC; HON. DAVE DURENBERGER, CHAIRMAN, SUBCOMMITTEE ON HEALTH, U.S. SENATE COMMITTEE ON FINANCE; DOUGLAS WILLIAMSON, M.D., PRESIDENT, OUTPATIENT OPHTHALMIC SURGERY SOCIETY, VENICE, FL, ACCOMPANIED BY DAVID McINTYRE, SECRETARY TREASURER, OUTPATIENT OPHTHALMIC SURGERY SOCIETY; JAMES AQUAVELLA, M.D., ASSOCIATE SECRETARY FOR HEALTH PLANS, AMERICAN ACADEMY OF OPHTHALMOLOGY, ROCHESTER, NY; AND JEROME BETTMAN, M.D., CHAIRMAN, ETHICS COMMITTEE, AMERICAN ACADEMY OF OPHTHALMOLOGY, WOODSIDE, CA

STATEMENT OF GORDON SMITH

Mr. SMITH. I consider it an honor to speak before you today, Chairman Pepper, on the subject of intraocular lenses. I commend you and your staff members for wanting to examine the relationships between the manufacturers of intraocular lenses and the ophthalmic community, as well as the Government's role in reimbursing both hospitals and physicians for the cost of lenses within the field of cataract surgery.

I am the administrator of the Eye Foundation Hospital in Birmingham, AL, the only hospital in the State dedicated exclusively to treating patients with eye-related problems. In 1984, approximately 20,000 patients were treated on an ambulatory basis; 4,200 surgical procedures were performed by over 30 ophthalmologists. Of these procedures, 1,500 were cataract extractions with IOL implantations. Seventy-five percent of this number, or approximately 1,000 patients, were 65 and over in age and recipients of the Medicare Program.

Prior to going on the prospective payment system, we knew the hospital would lose approximately $450 on DRG 39, or $450,000, in 1985. For a hospital which experienced less than $300,000 on its bottom line as retained earnings in fiscal year 1983, this was going to be a financial disaster unless major changes were made in how we conducted our business. In order to survive, we had to examine the many cost elements for the care we provide to 40 percent of our inpatient population. We discovered that approximately 28 percent of our fixed payment of $1,295, or $350, was for the purchase of the IOL. We also knew that the manufacturing costs of lenses were approximately $25. For this reason, we felt reasonably certain that in order to survive the reimbursement loss of DRG 39, we would have to change our purchasing methods with this particular product. In conjunction with the local Hospital Council, we and other hospitals in the area purchased through bid approximately 2,000 intraocular lenses. As a result, the cost of the IOL's had dropped to an average purchase price of $229.

The medical staff and the administration worked closely together on several cost reduction strategies for the first 6 months under the DRG's; many changes were made to reduce our losses to a break-even point by January 1985 for DRG 39. Our accumulative loss per average case ended up being approximately $135 as of March 31, 1985. In May, the Peer Review Organization for the State of Alabama mandated that all lens implants be managed on an outpatient basis. Now our losses are being offset by cost reimbursement under Part B of the Medicare Program.

With this as a background, I would like to cover four major subjects relative to IOL's and the purpose of our meeting today; namely, problems that I see in the reimbursement methods in the Medicare Program, the effects of group buying, examples of questionable sales practices in the IOL industry, and the probable cost of these practices for the Medicare Program and, in turn, the taxpayer. We also have a few recommendations that you may want to consider to alleviate some of these problems.

I happen to believe that what has taken place in the pacemaker industry is also true of the intraocular lens industry. That is, the lens manufacturers have taken full advantage of some ill-conceived Medicare reimbursement regulations. Under current Medicare regulations, the physician can bill separately for the implanted item—whether it be a pacemaker, IOL, or hip prosthesis. Furthermore, it is legal for a physician to accept a gift or inducement to use the lens of Company X as long as it is "properly disclosed and appropriately reflected in the costs claimed or charges made." As a result of this loophole, many very creative marketing schemes have developed, which I will discuss in a few minutes.

In February 1984, letters were sent to physicians throughout the country from the Department of Health and Human Services regarding rebates, kickbacks, and/or free goods to physicians and hospitals as inducements to purchase intraocular lenses. It refers to fraud and abuse under section 1877(B) of the Social Security Act. In this letter, the inspector general's office in essence has condoned gifts, rebates, or what some would call kickbacks, as long as the physician reports the value of it. This, to me, does not make any sense whatsoever.

I would also encourage you to read a letter written in September 1983 to the physician members of the American Lens Implant Society from Dr. Manus Kraff, its past president, on the subject of discounts, rebates and bonuses offered to physicians by the lens manufacturers. It is attached to my testimony as the Attachment D.

Dr. Kraff stated in a symposium given in March 1983 to members of the Society:

> Discounts, rebates, and bonuses have recently taken many forms—free lenses, when a set quota are purchased, free equipment, when a surgeon agrees to purchase a quota or have a hospital do so, cash payments based upon a prospective or prior volume of lenses purchased, et cetera. It is not illegal for the manufacturers to offer these discounts, rebates, or bonuses. Indeed, third-party reimbursers encourage all direct and indirect price reductions as long as they are passed along to the reimburser. But some of these programs seem designed by the manufacturers to facilitate criminal deception by surgeons to reimbursers. All of them at least make it difficult for the surgeon to pass the discounts on to the reimbursement program by law. If you get a free piece of equipment, how can you prorate that free piece of equipment into the cost of each cataract operation which you put an intraocular lens in and show that discount to Medicare? I don't know how you can do that.

Next, I would like to share with you our experiences with bidding intraocular lenses through a group buying process. As stated earlier, the Birmingham Regional Hospital Council sent out bids for 2,000 intraocular lenses to a number of known manufacturers. The bids came in with a discount range from 15 to 58 percent. One company—I will call Company E—submitted a bid with no discount. They were confident our medical staff would not alter their loyalties to that particular manufacturer due to a lesser price. In the first 60 to 90 days, a number of physicians did switch their purchases from a lens made by Company E to another manufacturer which did indeed discount their lenses.

In October 1984, Company E's representative came to me and offered a 20 percent discounted contract if I would commit to an annual volume of 700 lenses. That same week, I received information from another hospital that showed Company E offered this hospital a 30-percent discount for the last 7 or 8 months. The salesman was somewhat embarrassed with this information and came back with a 30-percent discount on all their nonultraviolet lenses. They would not offer us a discount on the ultraviolet lenses.

It was either that option or having a 20-percent discount across the board. We decided to go for the 30-percent discount on the nonultraviolets. Their market share, interestingly enough, had increased from 12 to 48 percent of all lenses we bought this year. With that volume, and considering their new price, we would have saved $95,000 from this one manufacturer alone as of June 30, 1985.

We anticipate using over 1,500 intraocular lenses in 1985 with an annualized savings, as a result of group buying, of $195,000. What would happen if all eye hospitals in the United States could achieve this goal?

Recognizing the effects of DRG 39, several administrators of eye hospitals met in June 1983 and formed the American Association of Eye and Ear Hospitals; 15 of our 20 members joined with the Consortium of Jewish Hospitals based in Chicago, IL, to do group buying in five specific areas within the field of ophthalmology. The purchase of intraocular lenses was first on our agenda.

We have been successful in watching lenses drop to as low as $80 with some manufacturers; most discounts were 40 to 60 percent off list price. It was very interesting to note that Company E would give the same 30-percent discount that was finally offered in Birmingham—even when Company E was offered a committed volume of 5,000 lenses from the consortium. We think that, assuming a fixed price method of reimbursement will remain in effect, physicians will once again become price-sensitive to help the hospital and in turn change their loyalties from Company E to other lens manufacturers with less costly lenses.

Members of the consortium will purchase approximately 40,000 to 45,000 intraocular lenses in 1985. To the best of our knowledge, it is the largest buying group that has concentrated on the group buying of supplies and equipment for ophthalmology in the United States. If it were not for fixed price reimbursement, eye hospitals would not have pursued this relationship with the consortium.

The fixed price method of reimbursement under the DRG's gives us an incentive to lower our costs with the understanding that we can retain any net gains made under this new method of reimbursement. We at the Eye Foundation Hospital have seen the average charge for a patient undergoing cataract surgery decrease from $3,200 in 1983 to $2,097 in March 1985.

We also learned that lens manufacturers encourage physicians to do cataract surgery on an outpatient basis so there will be no obligation to decrease the price of the lens. As long as the lens remains as a passthrough under part B, whether it be billed by a hospital, ambulatory surgery center, or a physician, I do not believe lens prices will decrease substantially.

After cataract surgery in Alabama was mandated by the Peer Review Organization to be done on an outpatient basis, physicians began to lose interest in lowering costs and utilizing less costly intraocular lenses. One physician said to me, "Gordon, what difference does it make if we use a $425 IOL as opposed to a $125 IOL? The Government will pay for it, anyway." Unfortunately, I had to agree with his assessment of the problem.

I would like to share with you one or two examples of unethical or questionable sales practices observed in different parts of the country by the different lens manufacturers in the last 18 months. These represent a few examples that I have been made personally aware of by ophthalmologists, sales representatives and other hospital administrators.

Company X sells lenses to Dr. Y; Dr. Y sends the invoice to the fiscal intermediary for reimbursement—he will be paid 80 percent of the invoiced amount. Dr. Y also sends a copy of the invoice to the hospital where he implants the IOL and asks the hospital to reimburse him for just one-half of the cost of the lens. The hospital is not aware of the fact that Dr. Y is being reimbursed for 80 percent of the lens from Company X.

Company X has their sales agent promote cataract surgery in a certain area by paying 15 or 20 referring optometrists a $75 or $100 "referral fee for postoperative services" they render for the patient that they would refer to Dr. Y. Of course, Dr. Y uses the lenses of Company X. The "postoperative care fee" is included with the invoice price of the lens which is a passthrough under current Medicare regulations. Dr. Y benefits significantly from the increase in the volume of referred surgical cases.

Company X loans $20,000 to a charitable foundation that is owned by the Academy of Ophthalmologists in a particular State. As ophthalmologists in that State utilize Company X lenses, each lens will carry with it a $100 credit for loan repayment. The foundation money can be used at the discretion of the ophthalmologists in that State.

I have other samples, but in the interests of time I will skip over them.

In summary, the opportunities for fraud and abuse are limited only to the imagination of those involved. One physician candidly told me that, "every company offers a deal of some type. The question is, what do you want or need? The choices are yours."

If 1 million lens procedures are done in the United States in 1985, and 80 percent of these patients are Medicare recipients, and there are $75 to $100 of questionable marketing costs built into the price of each lens, the Medicare Program and, in turn, the taxpayer is paying $60 million to $80 million more than necessary, in my opinion, for intraocular lenses.

Chairman Pepper, I hope today's hearings will result in some major changes in the system. As the representative of the American Association of Eye and Ear Hospitals, we have some suggestions.

First, the cost of the IOL should be included in a fixed price facility fee whether the implant be done on an inpatient or outpatient basis. If the cost of cataract surgery can be decreased by 33 percent in Birmingham due to a fixed price method of reimbursement, that same result will be experienced throughout the country.

Second, I don't think a physician should be allowed to bill separately for the implant, and no exceptions should be made for section 1877(B) of the Social Security Act. This loophole should be removed.

Third, the role of the Peer Review Organization should be to review the clinical indications for cataract surgery done in either the inpatient or outpatient setting. The PRO's have pushed cataracts to the outpatient setting, and most hospitals accepted because they would be reimbursed their cost which is as much as $500 more than the DRG payment for inpatient care.

Finally, I think it should be a physician's choice to determine whether or not the patient requiring a lens procedure should be done on an inpatient basis or an outpatient setting.

Thank you for the opportunity to speak before you today. If you have any questions, I will be glad to address them.

Thank you.

[The prepared statement and attachments of Mr. Smith follow:]

PREPARED STATEMENT OF GORDON SMITH, MEMBER, BOARD OF DIRECTORS, ASSOCIATION OF EYE AND EAR HOSPITALS, AND EXECUTIVE DIRECTOR, THE EYE FOUNDATION, BIRMINGHAM, ALABAMA

I consider it an honor to speak before you today, Chairman Pepper, on the subject of intraocular lenses. I commend you and your staff members for wanting to examine the relationships between the manufacturers of intraocular lenses and the ophthalmic community as well as the government's role in reimbursing both hospitals and physicians for the cost of lenses within the field of cataract surgery.

I am the administrator of the Eye Foundation Hospital in Birmingham, Alabama, the only hospital in the state dedicated exclusively to treating patients with eye-related problems. In 1984, approximately 20,000 patients were treated on an ambulatory basis; 4,200 surgical procedures were performed by over 30 ophthalmologists. Of these procedures, 1,500 were cataract extractions with IOL implantations. Seventy-five percent of this number, or approximately 1,000 patients, were 65 and over in age and recipients of the Medicare program.

Prior to going on the Prospective Payment System, we knew the hospital would lose approximately $450 on DRG 39 or $450,000 in 1985. For a hospital which experienced less than $300,000 on its bottom line as retained earnings in fiscal year 1983, this was going to be a financial disaster unless major changes were made in how we conducted our business. In order to survive, we had to examine the many cost elements for the care we provide to 40% of our inpatient population. We discovered that approximately 28% of our fixed payment or $350 was for the purchase of the IOL. We also knew that the manufacturing costs of lenses were approximately $25. For this reason, we felt reasonably certain that in order to survive the reimbursement loss of DRG 39, we would have to change our purchasing methods with this particular product. In conjunction with the Birmingham Regional Hospital Council, we and other hospitals in the area purchased through bid approximately 2,000 intraocular lenses. As a result, the cost of the IOL's had dropped to an average purchase price of $229.

The medical staff and the administration worked together on several cost reduction strategies for the first six months under the DRG's; many changes were made to reduce our losses to a break-even point by January 1985 for DRG 39. Our accumulative loss per average case ended up being approximately $135 as of March 31, 1985. In May, the Peer Review Organization for the state of Alabama mandated that all lens implants be managed on an outpatient basis. Now our losses are being offset by cost reimbursement under Part B of the Medicare program. (Attachment A)

With this as a background, **I would like to cover four major subjects relative to IOL's and the purpose of our meeting today; namely, problems that I see in the reimbursement methods in the Medicare system, the effects of group buying, examples of questionable sales practices in the IOL industry, and the probable cost of these practices for the Medicare program and in turn the taxpayer. I have a few recommendations that you may want to consider to help some of these problems.**

In the February 27, 1984, issue of FORBES an article entitled "Everybody's Money" was published in reference to the corruption that existed within the pacemaker industry (Attachment B). I would like to share with you parts of this particular article.

"There is a growing evidence of corruption in the pacemaker business.

> The doubt centers on how pervasive the wrongdoing is. Some pacemaker executives minimize its extent and assert their business has become a scapegoat. 'We are being used to accomplish something (cost reduction) in Medicare.' Says Russell Chambers, Chairman of InterMedics, 'I think you really need the facts.'" Yet the facts that are coming to light hardly support a Pollyannaish view. Corruption in the business seems hardly a question of isolated incidents or a few rotten apples in the sales force. The facts are emerging now in courts around the land. A pacemaker firm in California has been indicted for Medicare fraud. An executive of another firm fell into the clutches of the FBI and since has been indicted.". . . The article goes on and discusses some of the fraud and abuse practices that have occurred in the pacemaker industry. The last paragraph of this article is also of interest. "Marketing has created the most fat in the pacemaker business. And because tax money--that is, everybody's money--has financed it, the spending has become nobody's responsibility. When salesmen and doctors feather each other's nests, it amounts to an extreme example of padding an insurance claim or an expense account. Somebody else always pays the bill. Now that the government is introducing some economy measures in Medicare, some of the fat may disappear. Let's hope so."

Ladies and gentlemen, I happen to believe that what has taken place in the pacemaker industry is also true of the intraocular lens industry. That is, the lens manufacturers have taken full advantage of some ill-conceived Medicare reimbursement regulations. Under current Medicare regulations the physician can bill separately for the implanted item--whether it be a pacemaker, IOL, or hip prosthesis. Furthermore, it is legal for a physician to accept a gift *or inducement to use the lens of Company X as long as it is "properly disclosed and appropriately reflected in the costs claimed or charges made. As a result of this loophole, many very creative marketing schemes have been developed which I will discuss in a few minutes.*

In February 1984, letters were sent to physicians all over the country from the Department of Health and Human Services regarding rebates, kickbacks, and or free goods to physicians and hospitals as inducements to purchase intraocular lenses (Attachment C). It refers to fraud and abuse under Section 1877 (B) of the Social Security Act. In this letter, the Inspector General's office in essence has condoned gifts, rebates, or what some would call kickbacks, as long as the physician reports the value of it! This does not make any sense whatsoever.

I would also encourage you to read a letter written in September, 1983, to the physician members of the American Lens Implant Society from Dr. Manus Kraff, its president, on the subject of discounts, rebates and bonuses offered to physicians by the lens manufacturers (Attachment D). Dr. Kraff had stated in a symposium given in March of 1983 to members of the Society,

> ***"Discounts, rebates, and bonuses have recently taken many forms—free lenses, when a set quota are purchased, free equipment, when a surgeon agrees to purchase a quota or have a hospital do so, cash payments based upon a prospective or prior volume of lenses purchased, etc. It is not illegal for the manufacturers to offer these discounts, rebates or bonuses. Indeed, third party reimbursers encourage all direct and indirect price reductions as long as they are passed along to the***

reimburser, but some of these programs seem designed by the manufacturers to facilitate criminal deception by surgeons to reimbursers. All of them at least make it difficult for the surgeon to pass the discounts on to the reimbursement program by law. If you get a free piece of equipment, how can you prorate that free piece of equipment into the cost of each cataract operation which you put an intraocular lens in and show that discount to Medicare? I don't know how you can do that."

I happen to agree with Dr. Kraff. I am not sure how an ophthalmologist could prorate the value of a a Mercedes Benz, for instance, or a trip to Europe against x number of lenses he will implant in the next three years and submit to the fiscal intermediary a dollar discount on the invoice for the IOL.

Next I would like to share with you our experiences with bidding intraocular lenses through a group buying process. As stated earlier, the Birmingham Regional Hospital Council sent out bids for 2,000 intraocular lenses to a number of known manufacturers. Results were as follows:

1984 Annual Saving on IOL's as a Result of Group Purchasing

Company	% Discount	Annual Savings to EFH
A	15%	$ 3,300
B	58%	50,000
C	20%	28,000
D	25%	18,000
E*	No Discount at first; later a 30% discount was offered on non-UV IOL's	95,000
		$194,300

Company E submitted a bid at list price; that is, they didn't discount at all, because they were confident our medical staff would not alter their loyalties due to a lesser price. In the first 60-90 days a number of physicians switched their purchases from a lens made by Company E to another manufacturer which did indeed discount their lenses.

In October of 1984, Company E's representative came to me and offered a 20% discounted contract if I would commit to an annual volume of 700 lenses. That same week I received information from another hospital that showed Company E offered this hospital a 30% discount for the last seven or eight months. The salesman was somewhat embarrassed with this information and came back with a 30% discount on all their non-ultraviolet lenses. They would not offer us a discount on the ultraviolet lenses. It was either that option or having a 20% discount on all lenses. We decided to go for the 30% discount on the non-ultraviolets. Their market share, interestingly enough, had increased from 12% to 48% of all lenses we bought this year. With that volume, and considering their new price, we would have saved approximately $95,000 from this one manufactuer alone as of June 30, 1985.

We anticipate using over 1,500 intraocular lenses in 1985 with an annualized savings, as a result of group buying, of $195,000! What would happen if all eye hospitals in the U.S. could do this?

Recognizing the effects of DRG 39, several administrators of eye hospitals met in June of 1983 and formed the American Association of Eye and Ear Hospitals. Fifteen of our twenty members joined with the Consortium of Jewish

Hospitals based in Chicago, Illinois, to do group buying in five specific areas within the field of ophthalmology. The purchase of intraocular lenses was first on our agenda. We have been successful in watching lenses drop to as low as $80 with some manufacturers; most discounts were 40-60% off list price. It was very interesting to note that Company E would give the same 30% discount that was finally offered in Birmingham--even when Company E was offered a committed volume of 5,000 lenses from the Consortium. We think that, assuming a fixed price method of reimbursement will remain in effect, physicians will once again become price sensitive to help the hospital and in turn change their loyalties from Company E to other lens manufacturers with less costly lenses.

Members of the Consortium will purchase approximately 40,000 to 45,000 intraocular lenses in 1985. To the best of our knowledge, it is the largest buying group that has concentrated on the group buying of supplies and equipment for ophthalmology in the United States. If it were not for fixed price reimbursement, eye hospitals would not have pursued this relationship with the consortium. The fixed price method of reimbursement under the DRG's gives us an incentive to lower our costs with the understanding that we can retain any net gains made under this new method of reimbursement. We at the Eye Foundation Hospital have seen the average charge for a patient undergoing cataract surgery decrease from $3,200 in 1983 to $2,097 in March of 1985.

We find that lens manufacturers encourage physicians to do cataract surgery on an outpatient basis so there will be no obligation to decrease the price of the lens. As long as the lens remains as a pass-through under Part B, whether *it be billed by a hospital, ambulatory surgery center, or a physician, I do not believe lens prices will decrease substantially.*

After cataract surgery in Alabama was mandated by the Peer Review Organization to be done on an outpatient basis, physicians lost interest in lowering costs and utilizing less costly intraocular lenses. One physician said to me, "Gordon, what difference does it make if we use a $425 IOL as opposed to a $125 IOL? The government will pay for it anyway." Unfortunately, I had to agree with his assessment of the problem.

I would like to share with you some examples of unethical or questionable sales practices observed in different parts of the country by the different lens manufacturers in the last 18 months. *These represent a few examples that I have been made personally aware of by ophthalmologists, sales representatives and other hospital administrators.*

I. *Company X sells lenses to Dr. Y; Dr. Y sends the invoice to the fiscal intermediary for reimbursement (he will be paid 80% of the invoiced amount). Dr. Y also sends a copy of the invoice to the hospital where he implants the IOL and asks the hospital to reimburse him for just one-half of the cost of the lens. The hospital is not aware of the fact that Dr. Y is being reimbursed for 80% of the lens from Company X.*

II. *Company X asks Dr. Y to purchase their IOL's to be implanted in his ambulatory surgery center. Dr. Y agrees, especially when he is offered any one of the following options:*

A. *A hundred dollars worth of supplies will arrive at the Ambulatory Surgery Center as a part of their buying agreement. There will be an invoice for $450 for the IOL and a separate invoice for $20 for the supplies. Medicare will reimburse Dr. Y for 80% of the $450. Or*

B. *A key is sent in the mail to Dr. Y's home address to a furnished condominium for he and his family to visit in the Caribbean. The condominium in all likelihood belongs to a corporate executive of Company X. Or*

C. *An all expense paid ski or fishing trip for Dr. Y and his family to join two or three other colleagues and their families. This would be called an educational meeting. This is often followed by a $50 "consulting fee" that will be regularly paid by the sales representatives (more often than not a manufacturer's representative or independent contractor with Company X; usually not an employee) for each lens implanted by Dr. Y.*

III. *Company X has their "sales agent" promote cataract surgery in a certain area by paying fifteen or twenty referring optometrists a $75 or $100 "referral fee for post-operative services" they render for the patient that they would refer to Dr. Y. Of course, Dr. Y uses the lenses of Company X. The "post-operative care fee" is included with the invoice price of the lens which is a pass-through under current Medicare regulations. Dr. Y benefits significantly from the increase in the volume of referred surgical cases.*

IV. *Company X "loans" $20,000 to a charitable foundation that is owned by the Academy of Ophthalmologists in a particular state. As ophthalmologists in that state utilize Company X lenses, each lens will carry with it a $100 credit for loan repayment. The foundation money can be used at the discretion of the ophthalmologists in that state.*

V. *For every lens provided by Company X and used by implant surgeon, Dr. Y, Company X will purchase $100 of shares of a specified stock on behalf of Dr. Y's son or daughter. These shares will be sent to Dr. Y's home on a quarterly basis.*

VI. *For each lens provided by Company X that will be used by Dr. Y in any hospital or ambulatory setting, $100 will be deposited in a Cayman Island bank account in the name of Dr. Y or any member of his family. Once again, this inducement is more often than not offered by an independent contractor or sales agent representing Company X.*

In summary, the opportunities for fraud and abuse are limited only to the imagination of those involved. One physician candidly told me that "every company offers a deal of some type. . . .The question is, what do you want or need? . . . .The choices are yours!"

If 750,000 lens procedures are done in the United States in 1985 and 80% of these patients are Medicare recipients and there are $75 - $100 of questionable marketing costs built into the price of each lens, the Medicare program and, in turn, the taxpayer is paying $45 - $60 million more than necessary, in my opinion, for intraocular lenses.

Chairman Pepper, I hope today's hearings will result in some major changes in the system; as the representative of the American Association of Eye and Ear Hospitals, we recommend the following:

First, the cost of the IOL should be included in a fixed price facility fee whether the implant be done on an inpatient or outpatient basis. If the cost of cataract surgery can be decreased by 33% in Birmingham due to a fixed price method of reimbursement, that same result will be experienced throughout the country.

Second, I don't think a physician should be allowed to bill separately for the implant, and no exceptions should be made for Section 1877 (B) of the Social Security Act. This loophole should be removed.

Third, the role of the Peer Review Organization should be to review the clinical indications for cataract surgery done in either the inpatient or outpatient setting. The PRO's have pushed cataracts to the outpatient setting and most hospitals accepted because they would be reimbursed their costs which is as much as $500 more than the DRG payment for inpatient care.

Finally, I think it should be a physician's choice to determine whether or not the patient requiring a lens procedure should be done on an inpatient basis or an outpatient setting.

Thank you for the opportunity to speak before you today. If you have any questions, I will be glad to address them. Thank you.

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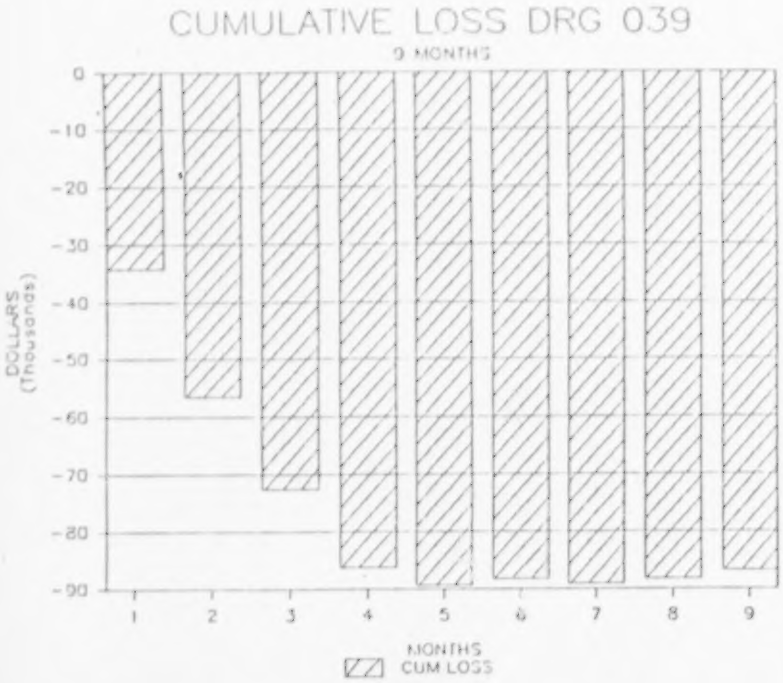
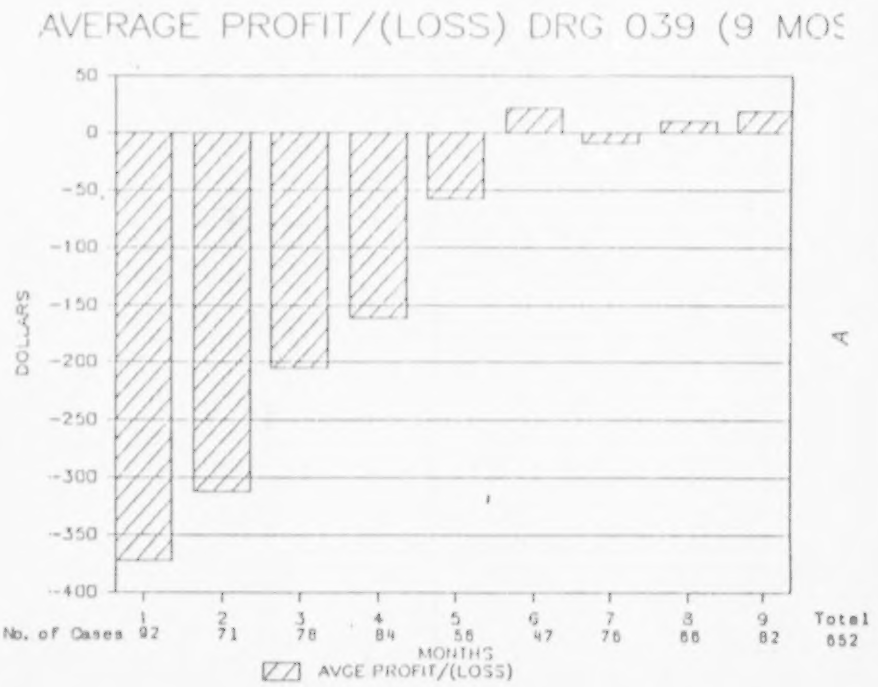
PROGRESS MADE TOWARD LOWERING THE LOSS/DRG 39

July–March, 1985





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Pacemakers have saved thousands of lives. But have they also contributed to inflation, the federal budget deficit and the looming bankruptcy of Medicare?

Everybody's money

By Robert McGough

CARDIOLOGIST BRENDAN PHIBBS is angry. "The money fever in this kind of stuff," he says. "You've got to see it to believe it!" By "this kind of stuff" he means pacemaker sales efforts—and kickbacks to doctors.

There is growing evidence of corruption in the pacemaker business. The doubt centers on how pervasive the wrongdoing is. Some pacemaker executives minimize its extent and assert their business has become a scapegoat. "We're being used to accomplish something (cost reduction) in Medicare," says Russell Chambers, chairman of Intermedics Inc. "I think you really need the facts."

Yet the facts that are coming to light hardly support a Pollyannaish view. Corruption in the business seems hardly a question of isolated incidents or a few rotten apples in the sales force. The facts are emerging now in courts around the land. A pacemaker firm in California has been indicted for Medicare fraud. An executive of another firm fell into the clutches of the FBI and since has been indicted. Investigations continue, and more indictments are likely. Even civil suits involving pacemaker corruption are being pursued.

The probes occur against a backdrop of sharply rising prices on pacemakers. Over the past decade the price has risen from $1,000 to as high as $5,000 a unit. The increases have contributed to inflation, the federal deficit and the looming bankruptcy of Medicare. This, despite aggressive competition among a half-dozen sizable firms.

"Nobody questioned the cost of these things," says a federal agent. Oddly enough, he adds, a pacemaker costing $4,000 in Seattle will cost only $3,000 in Vancouver.

Dr. Phibbs calls fees for the pacemaker operation "exorbitant"—as much as $2,200 for a simple operation performed in less than an hour. Per hour, that's comparable with fees for open-heart surgery, a vastly more complicated procedure that pacemaker implants no longer require.

What warps pacemaker prices? The answer is Medicare. Pacemaker recipients are usually old, and Medicare pays for two-thirds of implants. Doctors, hospitals and pacemaker companies have discovered that Medicare pays the price, no matter how high.

The industry was once dominated by Medtronic, Inc. of Minneapolis. Still the largest company, Medtronic now has only half of what once was an 80% market share. In the early 1970s Intermedics, of Freeport, Tex., among others, brought out an improved battery for pacemakers, reducing the need for reoperating. But Intermedics wasn't content to let the world beat a path to its door. It hired many of the best salesmen from Medtronic and other firms. The supersalesmen got commissions of 20% and more. That could mean $500 for a single sale, vs. $50 previously. Soon, say federal investigators, fatter commissions and salaries became standard.

With real money riding on a sale, and nothing to hold down prices, salesmen, at least at some companies, began splitting fees with doctors. Some money stuck to the doctors, some went to their favorite charities, but it all inflated Medicare costs.

Pacesetter Systems, a Sylmar, Calif. firm, was indicted last October along with its former president and two other officers for offering inducements to doctors. They all pleaded either guilty or *nolo contendere*. The indictments, and the paling of the new issues market, blocked an initial public offering of Pacesetter shares.

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Care Financing Administration

6325 Security Boulevard
Baltimore MD 21207

February [illegible], 1984

[illegible] H. Connell, MD
1420 N. Fifth St.
Phoenix, AZ 85004

Dear Sir/Madam:

It has come to our attention that some manufacturers may be offering rebates, kickbacks, and/or free goods to physicians and hospitals as an inducement to purchase intraocular lenses. Depending on the nature of the offer and the nature of the encouragement, these or similar arrangements may be in violation of a criminal statute, Section 1877(b) of the Social Security Act, that provides as follows:

"(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
    (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or
    (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or items for which payment may be made in whole or in part under this title,
shall be guilty of a felony and, upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
    (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or
    (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title,
shall be guilty of a felony, and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to--
    (A) a discount or other reduction in price obtained by a provider of services or other entity under this title if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this title; and
    (B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services."

C

Copy to Tom [illegible] [illegible]
& Wes Rogers

Manus C. Kraff, M.D.
President, AIOIS

AIOIS SYPOSIUM March 25, 1983

... marketing practices and rebates that are occurring and are continuing to occur, and your responsibility and your vulnerability.

Let me discuss some of these things with you that we have derived from legal counsel that it is unequivocally in violation of criminal law for an implant surgeon to receive a discount, a rebate, a bonus in connection with the purchase of intraocular lenses and fail to reflect that discount, rebate or bonus in claims to Federal reimbursers, such as Medicare or Medicaid.

Discounts, rebates and bonuses have recently taken many forms. Free lenses when a set quota are purchased, free equipment when a surgeon agrees to purchase a quota or have a hospital do so, cash payments based on a prospective or prior volume of lenses purchased, etc. It is NOT illegal for the manufacturer to OFFER these discounts, rebates or bonuses. Indeed, third party reimbursers encourage all direct and indirect price reductions as long as they are passed on to the reimburser! But some of these programs seem designed by the manufacturers to facilitate criminal deception by surgeons to reimbursers, and all of them at least make it difficult for the surgeon to pass the discounts on to the reimbursement programs by law. If you get a free piece of equipment, how can you prorate that free piece of equipment onto the cost of each cataract operation which you put an intraocular lens in and show that discount to Medicare? I don't know how you can do that.

The Implant Society has circulated two legal opinions to its entire membership from Washington legal counsel who have carefully researched the issue. The opinions are unqualified and unconditional in finding that it is a criminal law violation to fail to pass on the discounts, rebates and bonuses to medical reimbursers; you MUST pass those on to Medicare if Medicare is being charged.

Surgeons who participate in this practice for personal gain are taking enormous risks. They jeopardize their own reputation, professional and personal, and potentially are exposing themselves and their families to enormous liability. For, to profit illegally from discounts, rebates or bonuses by failing to report them to government reimbursers, also subjects the entire profession to injury and its reputation. You would be guilty by association; remember those words "guilty by association". The one who rides in the get-away-car is just as guilty even though he didn't do anything. These practices amount to welfare cheating. There is no way they can be viewed as anything but against the interests of the patients or the profession and the public. Presently, there are two ophthalmologists who are being investigated by the GAO. Now when companies give you a piece of paper stating that if you buy a certain number of intraocular lenses-you will receive a free piece of equipment, they should inform you right there and then on that piece of paper that you must pass that on to your patients or you are in violation of criminal law.

And I think that you should be made aware of that thing.

The Implant Society is determined to do all in its power within the constraints of law to stamp out this pernicious blight on our profession and our specialty. We've all heard about the investigations going on in the pacemaker industry. We're next! The AIOIS and the Scientific Advisory Board is devising a strategy and it will soon be announced and implemented. We will keep you informed as to what's going on. This is not a pleasant subject to discuss but I felt it certainly had to be brought up today.

Manus C. Kraff, M.D.
President, AIOIS
Program Chairman

AMERICAN INTRA-OCULAR IMPLANT SOCIETY
PRESIDENT

September, 1983

Dear AIOIS Member,

The Implant Society has often reminded members of the seriousness of failure to have included in claims to federal government reimbursers all discounts, rebates or bonuses provided by manufacturers of intraocular lenses.

AIOIS has published several legal opinions by its Washington counsel on this subject during the past year. Counsel has advised that:

1. An implant surgeon who submits a claim for lens purchase-reimbursement based upon assignment of the patient's Part B Medicare benefits, and fails to pass and disclose to the Medicare reimburser any discount, rebate or bonus related to the claimed lens purchase, commits a criminal violation of federal Medicare reimbursement law.
2. A Medicare Part B claim for intraocular lens reimbursement is paid at the rate of 80% of reasonable charges and must reflect any discounts, rebates or bonuses.

These and related requirements raise a number of questions. Answers to the questions have been sought from counsel and are based upon legal research and informal opinions received from government officials. They are summarized here.

Does it make a difference if patients submit their own Medicare Part B claims?

According to counsel, federal law requires that if an implant surgeon receives a discount, rebate or bonus in connection with the purchase of intraocular lenses, conscious failure to have the inducement reflected in a federal reimbursement claim violates

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the law, no matter who submits the claim. Thus, both "assigned" Medicare Part B claims (submitted by the surgeon) or "unassigned" claims (submitted by the patient) must reflect discounts, rebates or bonuses.

Are the requirements on Medicaid claims the same?

The identical language on disclosure of discounts, rebates or bonuses appears both in the Medicaid law and in the Medicare law.

What if a surgeon does not purchase intraocular lenses, but receives a payment or award from a manufacturer in return for recommending that a hospital purchase that manufacturer's lenses?

Counsel advises that the law could not be clearer on this point. It is criminally illegal to receive any inducements--including discounts, rebates or bonuses--in return for recommending that others purchase federally-reimbursed products or services. This unequivocally applies to an implant surgeon, for example, who is paid by an IOL manufacturer directly or indirectly to recommend that a hospital pharmacy stock that manufacturer's lenses. Federal officials advise that they are actively seeking to prosecute such cases of illegal referral payments or awards. This is one practice for which previous successful federal prosecutions have established a clear precedent for its illegality. In addition to the reimbursement law liability, serious ethical questions are obviously raised when an eye surgeon receives undisclosed payments or awards to recommend that a hospital purchase particular lenses and then uses these lenses when performing surgery at the hospital. One might also consider the impact upon a jury in a professional liability lawsuit in which it is disclosed that the defendant surgeon received secret payments or awards in connection with the hospital's purchase of an IOL that caused an adverse reaction upon its implantation by that surgeon.

What if a surgeon purchases IOLs and resells them to a hospital at a profit without reflecting applicable discounts, rebates or bonuses?

This situation raises more difficult legal questions that cannot be answered unequivocally, advises AIOIS counsel. If a surgeon acts as essentially a broker of intraocular lenses by purchasing them and then reselling them to a hospital at a profit, there may be no legal problems. But certainly, serious legal problems would be encountered if the surgeon then refers patients to the hospital and recommends implantation of the lenses that the surgeon has brokered. Federal reimbursement law on payments of awards for referrals, as well as ethical tenets, would prohibit a surgeon from concurrently brokering lenses to a hospital and then—using these lenses at the hospital in treating patients.

Do these laws on discounts, rebates or bonuses affect payments to surgeons for serving as investigators, for providing consulting services or for giving professional education courses?

Both FDA and the Medicare/Medicaid authorities have long approved of reasonable payments to clinical investigators for the special obligations required of them in the course of clinical studies. In the IOL situation, reasonable payments to "core study" investigators for their services beyond those routinely provided to patients in normal clinical practice would seem to raise no legal problems, according to counsel. On the other hand, extraordinarily high payments in relation to the services performed could raise reimbursement law questions if federal reimbursement is involved. Where an IOL "adjunct study" investigator is required to do little beyond normal clinical practice, payments by a manufacturer could be challenged as only thinly disguised discounts, rebates or bonuses. The same could be true with respect to unreasonably high lens manufacturer payments to an implant surgeon for providing consulting services or for giving professional education courses. What amount is "unreasonably high" cannot, of course, be defined but depends upon the circumstances in each situation.

How must discounts, rebates or bonuses be reflected in federal reimbursement claims?

Discounts, rebates or bonuses for intraocular lens purchases could take many forms. The surgeon may receive reduced price or free lenses after a certain number are purchased or agreed to be purchased. A check may be provided periodically to the surgeon based upon volume purchases. Reduced-price or free equipment, securities or travel may be provided if a requisite number of lenses are purchased or contracted for. None of these is automatically illegal for the lens manufacturer to provide or for the implant surgeon to receive. But they all must be reflected in reimbursement claims. Obviously it is difficult to reflect certain levels or kinds of discounts, rebates or bonuses in reimbursement claims, such as where free equipment is provided for lens purchases over a long period. To comply with the law, however, a reasonable effort must be made--with the cooperation of the manufacturer if possible--or the discounts, rebates or bonuses must be rejected.

In conclusion, it is clear that discounts, rebates or bonuses paid to implant surgeons raise many serious legal and ethical questions. AIOIS believes it serves all implant surgeons and their patients by a full airing of the subject, such as in this summary. Implant Society members who are interested may obtain copies of the comprehensive legal opinions on which this summary is based by contacting AIOIS headquarters.

Sincerely,

Manus C. Kraff, M.D.
President

Mr. **Pepper**. Thank you very much, Mr. Smith, for your excellent and able statement.

It presents a great challenge to us in the Congress to talk about trying to diminish the Federal Government's role in the people's business. Most of the time, Congress doesn't rush out trying to find something to do, to legislate about. We respond to demands from the Nation, when they want something done about situations like the one you are talking about, where citizens, in order to be able to see, are being exploited and ripped off by their fellow countrymen.

It is not easy, of course, to try to design legislation that will not interfere with legitimate practice, sales, and honorable characters. On the other hand, we are getting tired of people profiteering upon the suffering of their fellow citizens. If we are forced to, I think we can take steps that will perhaps prevent them from doing it, or punish them so that perhaps they won't want to repeat their wrongdoings.

I would like to hear the rest of the panel. We will hear the remainder of the panel before we question further.

The next witness is Dr. John Gilmore.

Doctor, we will be pleased to hear you.

STATEMENT OF JOHN GILMORE, M.D.

Dr. **Gilmore**. Good morning, Chairman Pepper.

It looks to me like there are some bad apples in the apple barrel. I think we have to get them out.

I am John Gilmore, an ophthalmologist in private practice in Santa Monica, CA. I am president of the Intra-Ocular Implant Society, a professional scientific and educational association with 4,500 members who are ophthalmologists involved mainly with cataract extraction and intraocular lens implantation.

The society has been at the forefront of Federal Government issues involving implants for over a decade. The Implant Society helped achieve a legislative compromise in the Medical Device Amendments of 1976 that placed intraocular lenses under the investigational controls of the Food and Drug Administration while remaining available to qualified physicians. The society helped FDA design and implement the largest clinical studies of any medical product in history that resulted from the congressional action, and has frequently answered the call of FDA for scientific and medical assistance on issues raised in the studies and in later FDA approval of intraocular lenses as safe and effective.

The Implant Society has also worked with Medicare authorities since 1977 on Federal reimbursement issues involving IOL's.

The society conducts symposia on all aspects of anterior segment eye surgery and publishes a highly regarded, peer-reviewed journal with paid circulation to over 7,000 eye surgeons. This is published bimonthly, or six times a year. Finally, the society frequently issues emergency communications to its member ophthalmologists when potential safety problems involving ophthalmic drugs and devices arise.

In short, AIOIS and its membership have, more than any other group, promulgated the safe widespread use of advanced surgical techniques and medical devices in the treatment of cataracts, toward the improved vision and lifestyle of millions of elderly Americans. Thanks to these developments, cataract patients can now expect to return quickly to a normal and productive life in business and in society.

Because it has proven to have such high levels of safety and effectiveness, IOL implantation several years ago became the standard vision correction mode in cataract surgery. With increased use of implants, symptoms of increased competition among manufacturers of the lenses have also appeared. The number of manufacturers has grown and now involves some 20 companies including many of the major medical device manufacturing firms. More aggressive marketing tactics have been implemented by some manufacturers in promoting IOL's to physician and medical institution customers, and many of these tactics having apparently been borrowed from other areas of the medical device industry.

In particular, discounts, rebates and bonuses offered by manufacturers to encourage the purchase of IOL's have become increasingly evident. AIOIS has been told that customers are being offered not only price reductions on IOL's, but other inducements, such as: rebates payable monthly, quarterly or annually based upon the volume of lens purchases; free IOL's; securities, such as stock or partnership interests; instrumentation, including expensive ultrasound or laser surgical equipment, earned through the long-term purchase of specified numbers of lenses; fees at exorbitant levels for the performance of even minor clinical study activities required for FDA compliance.

The Implant Society has been very concerned about the potential illegality of these discounts, rebates and bonuses; it had extensive legal research conducted, which is submitted for the hearing record today. In a series of over a dozen—actually 14—communications issued to its members over the past 3 years—I am saying we have sent out 4,500 communications on each occasion about the illegality of rebates in any form. We sent this out 14 times over the last 3 years.

The society has clearly and repeatedly advised of its position that Medicare laws may be violated if discounts, rebates or bonuses provided to encourage the purchase of intraocular lenses are not reported and reflected in claims submitted to Medicare, regardless of who submits the claims. Additionally, AIOIS has several times communicated with the manufacturers of intraocular lenses to urge them to be sure to comply with Medicare law requirements as the Society understands them.

It is easy to see that price reductions for medical items such as IOL's reimbursed by Medicare are a benefit to the Medicare program and therefore to taxpayers. Price reductions are certainly encouraged by Medicare. But when financial inducements for IOL purchases are not communicated and passed on to Medicare, there is the risk of private benefit at the expense of the Medicare program and, of course, the taxpayers. Some manufacturers, whether intentionally or not, may have encouraged the nonreporting of IOL discounts, rebates or bonuses by Medicare claimants through the structure or operation of their promotional programs.

AIOIS has attempted to obtain written clarification from the Federal Government on the Medicare law provisions applicable to discounts, rebates or bonuses. But because that law carries criminal penalties for convicted violators, the Inspector General's Office of the Health Care Financing Administration has been unwilling to issue written interpretations.

AIOIS urges this subcommittee to carefully consider the need to clarify precisely how the Medicare law applies to inducements for intraocular lens purchases so that IOL manufacturers, as well as their physician and medical institution customers, can be certain that they are in full compliance.

Beyond the issue of IOL pricing and Medicare claims is another related concern of the Implant Society that we hope this subcommittee will seriously pursue. It is that Peer Review Organizations have made it impossible for Medicare patients in many States to be admitted to hospitals for their cataract surgery under any circumstances. Society members pioneered the trend toward outpatient cataract and IOL surgery, in which the patient has no overnight stay. Surgery in that setting is ordinarily safe and effective. But there are sometimes good reasons why a patient should stay overnight for the surgery. These can include conditions of the patient's eyesight, such as vision in only one eye, general medical conditions such as heart, lung, kidney problems, or diabetes. They can also include patients with inadequate care at home or with long distances to travel for the surgery. Peer Review Organizations established last year in all States have negotiated quotas with Medicare for reducing hospital stays for cataract surgery. The quotas vary greatly. In Florida, for example, inpatient cataract surgery is to be reduced by 90 percent.

In their headlong rush to meet the quotas, many PRO's have determined to simply prohibit all cataract surgery admissions. Most have not developed the guidelines required by law to assure that a decision on admission for cataract surgery remains where it belongs—with the physician and the patient. AIOIS is aware of many circumstances where a patient's eyesight or health was seriously threatened because of PRO refusal to permit a hospital stay for cataract surgery.

The Medicare authorities should require PRO's to use sensible published guidelines to permit cataract and IOL surgery admission when it is best for the patient. AIOIS had petitioned Medicare for these guidelines; but the petition was denied. Recently, the Implant Society filed a lawsuit here in Washington to compel guidelines that would permit cataract patient hospital admission in circumstances of medical or personal need. Copies of the petition and lawsuit documentation are submitted for the subcommittee's record.

Our representatives have already worked closely with the subcommittee's staff on these issues, and they are prepared to continue to do so.

Thank you.

[The prepared statement and attachments submitted by Dr. Gilmore follow:]

PREPARED STATEMENT OF JOHN GILMORE, M.D., PRESIDENT, AMERICAN INTRA-OCULAR IMPLANT SOCIETY

Chairman Pepper and Subcommittee members, good morning. I am John Gilmore. I am an ophthalmologist in private clinical practice in Santa Monica, California and I serve as President of the American Intra-Ocular Implant Society, a professional scientific and educational association with 4,500 members who are ophthalmologists involved with anterior segment eye surgery, including cataract extraction and intraocular lens implantation.

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Because it has proven to have such high levels of safety and effectiveness, IOL implantation several years ago became the standard vision correction mode in cataract surgery. With increased use of IOLs, symptoms of increased competition among manufacturers of the lenses have also appeared. The number of manufacturers has grown and now involves some twenty companies including many of the major medical device manufacturing firms. More aggressive marketing tactics have been implemented by some manufacturers in promoting IOLs to physician and medical institution customers, many of these tactics having apparently been borrowed from other areas of the medical device industry.

In particular, discounts, rebates and bonuses offered by manufacturers to encourage the purchase of IOLs have become increasing evident. AIOIS has been told that customers are being offered not only price reductions on IOLs, but other inducements such as:

- Rebates payable monthly, quarterly or annually based upon the volume of lens purchases.
- Free IOLs given in return for the purchase of specified numbers of lenses.
- Securities, such as stock or partnership interests, issued to IOL purchasers.
- Instrumentation, including expensive ultrasound or laser surgical equipment, earned through the long-term purchase of specified numbers of lenses.
- Fees at exorbitant levels for the performance of even minor clinical study activities required for FDA compliance.

The Implant Society has been very concerned about the potential illegality of these discounts, rebates and bonuses; it had extensive legal research conducted, which is submitted for the hearing record today. In a series of over a dozen communications issued to its members over the past three years, AIOIS has clearly and repeatedly advised of its position that Medicare laws may be violated if discounts, rebates or bonuses provided to encourage the purchase of intraocular lenses are not reported and reflected in claims submitted to Medicare, regardless of who submits the claims. Additionally, AIOIS has several times communicated with the manufacturers of intraocular lenses to urge them to be sure to comply with Medicare law requirements as AIOIS understands them.

It is easy to see that price reductions for medical items such as IOLs reimbursed by Medicare are a benefit to the Medicare program and therefore to taxpayers. Price reductions are certainly encouraged by Medicare. But when financial inducements for IOL purchases are not communicated and passed on to Medicare, there is the risk of private benefit at the expense of the Medicare program and of taxpayers. Some manufacturers, whether intentionally or not, may have encouraged the non-reporting of IOL discounts, rebates or bonuses by Medicare claimants through the structure or operation of their promotional programs.

AIOIS has attempted to obtain written clarification from the federal government on the Medicare law provisions applicable to discounts, rebates or bonuses. But because that law carries criminal penalties for convicted violators, the Inspector General's office of the Health Care Financing Administration has been unwilling to issue written interpretations.

AIOIS urges this Subcommittee to carefully consider the need to clarify precisely how the Medicare law applies to inducements for intraocular lens purchases so that IOL manufacturers, as well as their physician and medical institution customers, can be certain that they are in full compliance.

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The Medicare authorities should require PROs to use sensible published guidelines to permit cataract and IOL surgery admission when it is best for the patient. AIOIS had petitioned Medicare for these guidelines; but the petition was denied. Recently, the Implant Society filed a lawsuit here in Washington to compel guidelines that would permit cataract patient hospital admission in circumstances of medical or personal need. Copies of the petition and lawsuit documentation are submitted for the Subcommittee's record.

Our representatives have already worked closely with the Subcommittee's staff on these issues; and they are prepared to continue to do so.

Thank you.

LAW OFFICES

JENNER & BLOCK

A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

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ONE IBM PLAZA
CHICAGO, ILLINOIS 60611
(312) 222-9350

MEMORANDUM

TO: American Intra-Ocular Implant Society

FROM: Jerald A. Jacobs
Jenner & Block

DATE: June 3, 1985

RE: Discounts, Rebates and Bonuses with the Purchase of Intraocular Lenses

The proliferation of intraocular lens manufacture and use in the United States during the past several years has led to certain marketing and sales practices by lens sellers which are intended to increase demand for their lenses; among these practices is the offering of discounts, rebates or bonuses to intraocular implant surgeons who purchase - or cause to be purchased by others such as hospitals - designated levels of intraocular lenses.

This memorandum considers: (i) the legality of the acceptance of intraocular lens discounts, rebates or bonuses by implant surgeons when analyzed under the Social Security Act or under the Food, Drug, and Cosmetic Act; (ii) the impact of physicians' administrative expenses in stocking intraocular lens inventories; and (iii) the legal implications of discounts, rebates and bonuses in alternative modes of reimbursement where a surgeon either (a) purchases lenses from manufacturers and then resells them to a hospital which seeks reimbursement for the cost of the lenses under Part A of Medicare, or (b) merely directs that the hospital purchase the lenses from the designated manufacturers. The related question of payments to surgeons by manufacturers for the services of the surgeons in acting as investigators is also considered. Finally, the impact of the prospective reimbursement system for hospitals is discussed.

I. Intraocular Lens Discounts, Rebates or Bonuses to Implant Surgeons

Based upon our review of the facts and upon our analysis of the applicable law, it is our opinion that:

> (1) There is no violation of law in acceptance of intraocular lens discounts, rebates or bonuses by implant surgeons when analyzed under the Social Security Act or under the Food, Drug, and Cosmetic Act; but that
>
> (2) Intraocular lens discounts, rebates or bonuses must be disclosed and passed on to third-party payers in the Medicare or Medicaid programs when the implant surgeons seek reimbursement; conscious failure to do so may be considered a criminal felony.

FACTS

Ophthalmic surgeons who perform cataract extraction surgery with the implantation of intraocular lenses as pseudophakia, or who effect implantation later as secondary procedures, often have as their patients individuals covered by third-party medical expense reimbursement plans which are part of the Medicare or Medicaid programs. Medicare is a federally-administered program covering the elderly and disabled; Medicaid is a state-administered program covering the indigent. Both programs follow reimbursement guidelines of the federal Health Care Financing Administration ("HCFA"). Intraocular lenses are available for purchase from over twenty manufacturers. Most are still classified as "investigational" by the Food and Drug Administration; but approximately two dozen specific styles of intraocular lenses have received premarket approval from FDA and are denominated "safe and effective" under certain conditions. It is estimated that some 600,000 to 750,000 cataract procedures are performed annually in the U.S. The average patient age is nearly 70; so most are covered by Medicare. Intraocular lenses range from $100 to $400 in price. There are two primary modes for the purchase of intraocular lenses for use by implant surgeons and subsequent reimbursement where patients are covered by reimbursement plans. In one mode, intraocular lenses are purchased by a hospital pharmacy for its own inventory, often at the request and to the order of ophthalmic surgeons who operate at the hospital. In this mode, reimbursement for a lens used in surgery at the hospital (as well as other hospital charges) is sought by the hospital, either from the patient or the patient's reimbursement plan. In the other mode, lenses are purchased by the implant surgeon for his or her own inventory. In this mode, reimbursement for a lens used by the surgeon (as well as for other surgical charges) is sought by the surgeon, either from the patient or the patient's reimbursement plan. Intraocular lens manufacturers have occasionally extended offers of discounts (lens purchase price reductions based upon quantity of lenses purchased or for purchase within specified time periods); rebates (lens purchase price reductions provided after a specified volume has been purchased) or bonuses (premiums or gifts provided in connection with one or more lens purchases). These sales inducements are generally offered to the purchaser of the intraocular lenses -- in one mode, the hospital pharmacy; in the other mode, the implant surgeon. They may also be offered to the physician who does not purchase lenses but recommends or requires the purchase by a hospital.

ANALYSIS

Both the Medicare and Medicaid programs are established under the Social Security Act. With respect to the Medicare program, Section 1877 of the Social Security Act (42 U.S.C. § 139nn(b)) provides that --

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing . . . any good . . . or item for which payment may be made . . . shall be guilty of a felony . . .

* * * *

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase any good . . . or item for which payment may be made . . . shall be guilty of a felony . . .

Similarly, with respect to the Medicaid program, the exact language prohibiting kickbacks, bribes or rebates is tracked. 42 U.S.C. § 1396h(b).

These provisions of the law were strengthened in 1977 by the Medicare-Medicaid Antifraud and Abuse Amendments to the Social Security Act (P.L. 95-142) in response to the perceived abuses of the reimbursement system by some medical practitioners. The Act specifically excludes from its prohibitions --

> a discount or other reduction in price obtained by a provider of services or other entity . . . if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider . . . (12 U.S.C. §§ 1395nn(b)(3) and 1396h(b)(3)).

As stated by the Congressional committee that drafted the legislation --

> The committee would encourage providers to seek discounts as a good business practice which results in savings to medicare and medicaid program costs. (House Report no. 95-393, Part II, at 53).

The wording of these statutory provisions, reinforced by the legislative history, suggests that there is nothing intrinsically illegal under the Social Security Act about the offering or receiving of discounts, rebates or bonuses for products such as intraocular lenses which are reimbursed under programs established by the Act. What is clear is that *knowing and willful* submission of false claims under the Medicare or Medicaid programs is a criminal felony. In addition, the language of the statute exempting from its coverage those instances of discounts or other price reductions that are properly disclosed and appropriately reflected in claims at least implies that *undisclosed price reductions not reported and reflected in claims* are illegal.

If they chose to be reimbursed themselves, implant surgeons must submit claims for reimbursement under Medicare or Medicaid programs for intraocular lenses that they purchase and implant in patients covered by the programs. Arguably, those claims are knowingly and willfully false if they do not reflect price reductions received by the surgeons as discounts, rebates or bonuses. Under this analysis, the implant surgeons commit a criminal felony in accepting the reductions without passing them on to the third-party reimbursers.

Testing this analysis through review of decided cases on this issue is difficult because little authority exists on the precise point. However, there have been cases brought under the pertinent sections of the Social Security Act. In those few cases, the courts have broadly construed the purview of the prohibitions: *United States* v. *Duz-Mor Diagnostic Laboratory, Inc.*, 650 F.2d 223 (9th Cir. 1981) (15% rebate in exchange for Medicare referrals constituted an "offering" of a bribe or kickback under the Act); United States v. Hancock, 604 F.2d 999 (7th Cir. 1979) (kickback defined as "a percentage payment . . . for granting assistance by one in a position to open up or control a source of income"); United States v. Ruttenberg, 625 F.2d 173 (1980) (no defense to a druggist paying monthly fees to nursing homes receiving Medicaid funds in return for drug business that cost of drugs was not increased by fee payments); and United States v. Perlstein, 632 F.2d 661 (6th Cir. 1980) (where court found there were no indications that supplier was selected for reasons other than "gifts" to the nursing home operator).

Further, in consultation with Health Care Financing Administration officials in the Fraud and Abuse Section, they have indicated that HCFA considers non-disclosed payments to physician-purchasers on supplies and equipment when the reimbursement is based upon the physician's cost to be illegal.

It is our opinion that it would be most prudent for implant surgeons to heed the broad language of the Social Security Act and its legislative history, especially since the legal consequence of violating those proscriptions were greatly increased in 1977. Violations are now considered criminal felonies. That broad language would not outlaw the acceptance of intraocular lens discounts, rebates or bonuses; but it would seem to require disclosure and passing on of those price reductions to third-party Medicare or Medicaid program payers.

II. Part B Medicare Reimbursement and Administrative Fees for Stocking Lenses

Concerning the possible impact of physicians' administrative expenses in stocking intraocular lens inventories, based upon our review of the law governing Part B Medicare reimbursement, it is our opinion that:

> (1) In general, Part B Medicare reimbursement centers around a determination of the reasonableness of charges by physicians, without regard to actual costs; therefore, administrative expenses of physicians are largely irrelevant in this context.
>
> (2) Although administrative costs could be considered a partial defense to a charge that a price reduction was not appropriately reflected in the costs claimed for charges made by a physician under Part B of Medicare, the statute appears to impose a separate and independent duty to disclose properly any discount or other reduction in price obtained by a physician from the supplier of intraocular lenses.

An understanding of these conclusions depends upon some knowledge of the quite complicated procedures for Part B Medicare reimbursement. An explanation of the general scheme is therefore provided here.

FACTS

Title XVIII of the Social Security Act (Medicare) includes two separate, but complimentary programs. Part A of the original Medicare program provides medically necessary in-patient care in a hospital, skilled nursing facility or at home. Basically, reimbursement under this part includes 100 percent (less a deductible) of reasonable costs. A more recent modification of the program provides reimbursement to hospitals for in-patient procedures on a prospective payment basis - but that modification may not greatly affect cataract surgery which is largely done on an outpatient basis.

Part B of Medicare is a voluntary, supplementary program covering 80 percent of reasonable charges for physicians' services and a number of other items and services not included in the basic Part A program. Individual beneficiaries of Part B must pay monthly premiums that are matched by contributions from the Federal government, an annual yearly deductible of $75, and 20 percent of reasonable charges as co-insurance on almost all covered items.

In addition~~,~~ on an individual basis, providers and suppliers can enter into an assignment with a beneficiary under which the supplier agrees to accept as his total fee the amount of Medicare reimbursement plus the 20 percent co-insurance and any outstanding part of the deductible that the patient must pay. A Part B claim can be sent in by a physician on the patient's behalf, a physician on his own behalf, if he has accepted an assignment, or the patient can submit a claim directly to Medicare.

All Medicare reimbursement is limited to treatments that are both "reasonable" and "medically necessary."

Reimbursement under Part A of the original Medicare program is based upon reasonable costs, which generally are actual hospital expenditures as shown on audited cost reports. Part B reimbursement, however, is based upon 80 percent of reasonable charges, as calculated by carriers for each region of the country based upon a complicated formula utilizing area prices (prevailing charges), individual prices (customary charges), and actual prices of services or supplies. Under Part B, "carriers" are insurance companies retained by the federal government to review and pay claims submitted by or on behalf of eligible beneficiaries. The government reimburses the carriers for the money they have paid out for Medicare reimbursement plus administrative costs incurred by the carriers in processing claims.

Legally, carriers must follow the laws governing Medicare and the specific requirements in the contracts they sign with the Federal government. In addition, the government's Medicare authority, HCFA, publishes a Medicare Carriers Manual that offers guidelines on carrier determination of reasonable charges.

The carriers manual defines "reasonable charge" as the lowest of the: (1) actual charge, (2) customary charge, and (3) prevailing charge. The actual charge is the amount of the bill submitted to the carrier for an individual service or device. Calculation of customary charges and prevailing charges is more complicated.

A customary charge is an individual physician's usual charge for a given medical service or device. Carriers calculate this charge each July, using actual charges for the service or item during the immediately preceding calendar year. Therefore, customary charges for the fee screen year running from July 1, 1984 to June 30 1985, for example, are based upon actual charges during the 1983 calendar year. Specifically, there must be at least three charges for a particular service or device; there is no maximum number. After ranking in ascending order charges for a particular service or device, the carrier determines the customary charge. This charge is the lowest charge that is high enough to include the median of the rank order charges from the year before. If there is an even number of charges, the customary charge is set mid-way between the dollar amounts for the two middle figures.

If there is a problem in calculating customary charges in this usual way, alternative methods may be used. Such difficulties can result from several factors. For example, charge data for the previous year may be unavailable or there may be less than the minimum number of three charges for an item during the required period. If a physician submits a charge that is unusually high or unusually low for an item or service, the carrier has discretion to disregard this charge in determining allowable customary charges.

Prevailing charges are the usual, most prevalent charges for an item or service in the local area. Carriers calculate prevailing charges by first accumulating the customary charges in the area for a particular service, listing them in ascending order, and weighing each by the number of times a service was provided by each supplier at a given price. Then, the prevailing charge is set at the level that is high enough to include the customary charge of the physician who furnished at least 75 percent of the services. For example, if 100 intraocular lenses were inserted in a given area, a carrier would rank the charges for these lenses in ascending order. Starting from the least expensive lens, the customary charge for the 75th lens becomes the prevailing charge. The HCFA Medicare Carriers Manual states that a minimum of four customary charges is needed to calculate a prevailing charge in this manner.

Carriers can use three alternative methods of calculating customary and prevailing charges if they cannot be determined in the usual manner. First, where available, a carrier can use price lists submitted by suppliers of services. Second, a carrier may use a relative value scale to compare a new service or one with less than three customary charges to existing services provided by physicians. The carrier would compare by degree of difficulty a new service to existing services, and set an appropriate price to be used as a customary charge. Third, carriers can use the "new man in town rule" to provide a customary charge for a physician without one when a prevailing charge for the service exists in the area. Unlike the prevailing charge, which is set at a level high enough to account for 75 percent of area billings for that service, the customary charge is set at a level high enough to include 50 percent of the charges in order to establish an average charge.

HCFA has directed reimbursement of certain standard laboratory procedures at the "lowest charge level." HCFA reasoned that because the quality of the tests and equipment did not vary significantly from one supplier to another, Medicare would set charge levels at the lowest price "at which such items and services are widely and consistently available in the locality." HCFA does not currently plan to expand this rule to other types of suppliers.

The Medicare Carriers Manual also states that, in addition to the methods outlined above, "other factors that are appropriate in judging inherent reasonableness should be taken into account" to establish reasonable charges. Only the income of the beneficiary is excluded specifically from such factors. Thus, carriers have a great deal of discretion regarding determination of reasonable charges.

Part B Medicare reimbursement of reasonable charges is subject to two general restrictions. First, "deluxe" or "experimental" items will not be reimbursed. That is, if a deluxe item is ordered, Medicare will only reimburse for the cost of a standard one. In early 1978, at the urging of AIOIS, Medicare decided to reimburse for intraocular lenses and lens implantation, despite their "investigational" status at FDA, because the reimbursement authorities agreed that lenses were not "experimental". Second, the reimbursement rate cannot be higher than the carrier (a private insurance company) would pay out under comparable circumstances for a comparable service to one of its own beneficiaries.

Prosthetic devices, including intraocular lenses, can be reimbursable under either Part A or Part B. In general, prosthetic devices (other than dental) that replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ, and replacements or repairs of these devices, are covered when furnished incident to physicians' services or on physicians' orders. Supplies necessary for effective use of prosthetic devices are also covered. The term "internal body organ" includes the lens of an eye. Reimbursable prostheses include post-surgical lenses - i.e., aphakic spectacles - used during convalescence from eye surgery in which the lens of the eye was removed. Permanent lenses - i.e., aphakic spectacles or intraocular lenses - that are required by an individual lacking the organic lens of the eye because of surgical removal or congenital absence are also covered. Lenses obtained on or after the beneficiary's date of entitlement to

Part B benefits are covered even though surgical removal of the crystalline lens occurred before entitlement. This includes both spectacles and intraocular lenses.

ANALYSIS

Basically, intraocular lenses can be reimbursed in three ways. First, if supplied by the hospital and used on an outpatient basis, lenses are reimbursable at 100 percent of reasonable cost, including administrative costs incurred. Second, if supplied by the hospital and used on an inpatient basis, the lens cost is included in the fixed prospective reimbursement payment to the hospital for all of its expenses in connection with the cataract procedure (that system is discussed later in this memorandum). Lastly, a surgeon who supplies the lens could bill separately for the lens charges and seek Part B Medicare reimbursement.

Under the latter reimbursement route, the charges need not be related to actual cost of the lens in order to be reimbursable. Instead, as outlined above, limits upon reimbursable charges stem from carrier calculation of reasonable charges. Thus, a physician will be reimbursed for 80 percent of his customary charge for surgery and the lens, unless such charge exceeds the prevailing charge in the area, in which case reimbursement consists of 80 percent of such prevailing rate. If a physician is the only one in an area who charges separately for a lens, a carrier could disallow such charge on the basis that it should be included in the surgery or hospital fee. Although a separate charge for the lens is possible, particularly if this is the practice in the area, it is extremely unlikely that a carrier would allow a separate administrative handling charge for the lens. In general, a charge for any prosthetic device must include cost of travel, fitting, labor, and other related costs. In addition, there is normally one prevailing charge for a particular service, without any bifurcation to take account of individualized costs such as those incurred in stocking lenses.

The statutory language, outlined in Part I of this memorandum, appears to impose two separate and independent conditions upon exclusions from conduct that would otherwise constitute a felony: reductions in prices must be "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider . . ." (emphasis added). Thus, it is possible that a physician who disclosed a lens reduction in price when seeking Medicare reimbursement could justify a reasonable charge that exceeds the cost of the lens on the basis that he has incurred considerable administrative costs in stocking lenses, assuming such charge does not violate the limits imposed by customary and reasonable charges. Nevertheless, while such administrative costs could be considered as a partial mitigating factor to a felony charge, if a physician accepts Medicare reimbursement for a lens on which he has received a rebate or other price reduction, proper disclosure of such rebate or price reduction is highly advisable in order to avoid such charges altogether.

III. Legal Implications of Discounts, Rebates or Bonuses in Alternative Modes of Reimbursement

It is not uncommon for a surgeon either (1) to purchase intraocular lenses from manufacturers and resell them to a hospital which seeks reimbursement for the cost of the lenses under Part A of Medicare; or (2) to direct that the hospital purchase the lenses from the designated manufacturers. In either situation, the hospital pharmacy will purchase the lenses at the request of the surgeon, who will then implant the lenses in patients at that hospital. A surgeon who buys lenses and sells them to the hospital or merely directs the hospital to buy the lenses may receive discounts, rebates or bonuses from lens manufacturers. When a surgeon fails to disclose and pass along such price reductions to the hospital, we have concluded:—

> (1) Criminal statutes forbid receipt by a surgeon of any remuneration, including discounts, rebates and bonuses from a manufacturer in return for purchasing or recommending the purchase of a lens if the price may be reimbursed in whole or in part by Medicare or Medicaid, unless such price reductions are disclosed and passed along in the surgeon's charges.
>
> (2) A surgeon who receives remuneration from an intraocular lens manufacturer in the form of discounts, rebates or bonuses in connection with purchases of lenses by the surgeon, and who then resells such lenses to a hospital without disclosing or passing along such price reductions,

> violates criminal felony provisions governing Medicare and Medicaid reimbursement if either program pays for the cost of the hospital purchases, especially if the surgeon recommends or directs the hospital purchase.

A related question concerns the legality of manufacturer payments to surgeon investigators of intraocular lenses. In this regard, we have concluded:

> (3) While reasonable payments by manufacturers to intraocular lens "core" investigators that are related to the services required above those necessary for normal patient care are legal, unreasonably large payments to "adjunct" investigators unrelated to the amount and value of such services are illegal and receipt may be considered a criminal felony.

In addition to the provisions of the Medicare portion of the Social Security Act quoted in Part I of this memorandum, there is an exception for any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services. 42 U.S.C. § 1395nn(b). The above exception, as well as other statutory references to Medicare, apply also to Medicaid.

A. Remuneration for Recommending the Purchase of a Lens

In the case of remuneration by a manufacturer to a surgeon who recommends or directs that a hospital purchase lenses from the manufacturer, the law is clear. If Medicare pays for the lenses in whole or in part, the reimbursement is illegal, subjecting both the manufacturer and the surgeon to potential criminal felony penalties (up to five years in jail and a $25,000 fine per offense). Under the statutory language previously quoted, it makes no difference whether a surgeon actively approaches a manufacturer and solicits payment or whether he passively receives payments offered by a manufacturer. Such payments are illegal whether they are made directly by a manufacturer to a surgeon or indirectly through an intermediary company or individual. Both open (overt) and secret (covert) payments are prohibited. The statutory language forbidding receipt of "any remuneration . . . in cash or in kind" certainly extends to any monetary payments, discounts, reductions in prices or free lenses, and very probably includes anything else of significant value, such as free equipment given in return for recommending lens purchases. While as a practical matter payments would likely not be made unless the surgeon's recommendations resulted in actual lens purchases, "recommending," not successful recommending, is what the statute expressly refers to.

The criminal penalties apply to remuneration in return for recommending purchases "for which payment may be made" by Medicare (emphasis added). Thus, if the purchase is one that is eligible for Medicare reimbursement, the statute would appear to apply even if such reimbursement never takes place.

The statutory limitation to "knowing and willful" receipt of remuneration offers a possible defense, but the knowledge and will that is required refers to awareness regarding the proscribed activities themselves (e.g., receipt of remuneration), not to any knowledge of the law itself. Although relevant in other contexts, the two exclusions from the statutory prohibitions previously quoted would not normally apply to the situation of a manufacturer payment to a surgeon in return for recommending lens purchases. Because under these circumstances the surgeon would neither purchase nor sell the lenses in question, it is difficult to see how the first exclusion for reductions in price "obtained by a provider of services or other entity" and properly disclosed and "reflected in the costs claimed or charges made" could be relevant. The second exclusion would only apply if the surgeon were a bona fide employee of the manufacturer, a provision that would be significant, if at all, only with regard to the separate issue, discussed below, of manufacturer payments to surgeon investigators of intraocular lenses.

Furthermore, even in cases involving lens purchases that are ineligible for Medicare reimbursement, manufacturer payments to surgeons in return for recommending lens purchases may constitute commercial bribery forbidden by Section 2(c) of the federal Robinson-Patman Act or similar state laws, especially if such payments have an anticompetitive impact on the market for lenses. See Metrix Warehouse, Inc. v. Daimler-Benz Aktiengesellschaft, 1982-2 Trade Cases ¶64,861, Civ. No. N-79-2066 (D. Md. June 4, 1982) and cases cited therein.

B. Purchase and Resale of Lenses By a Surgeon

More difficult legal questions arise in the situation of a surgeon who purchases lenses from a manufacturer, and then resells them to a hospital, which seeks reimbursement for the cost of the lenses under Part A of Medicare.

The described surgeon's conduct would appear potentially to violate two statutory prohibitions. First, cash or in kind rebates, kickbacks or other remuneration to surgeons from lens manufacturers may be considered to be received "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, . . ." 42 U.S.C. § 1395nn(b)(1)(A). [Subsection A.] Second, such remuneration can be interpreted as received "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under this subchapter, . . ." 42 U.S.C. § 1395nn(b)(1)(B). [Subsection B.]

1. Referral of an Individual

If a surgeon refers a patient to a hospital for implantation of a Medicare-reimbursed lens that the surgeon has sold to the hospital and for which lens the surgeon has received a rebate from the manufacturer, the criminal sanctions of subsection A would likely apply. This is because the remuneration to the surgeon could well be viewed as a direct or indirect payment in return for referring the patient to a hospital "for the furnishing or arranging for the furnishing of [an] item . . . for which payment may be made" by Medicare.

Although there are a number of potential defenses to a criminal charge under subsection A, none of these are persuasive. They are inconsistent with case law and the legislative history of the provision in question. (See discussion of cases in Part I.)

2. Remuneration for recommending the purchase or order of a lens

At least one court has stated that "[i]t is obvious from the language in the statute that the (A) and (B) subsections of ¶ 1396h(b)(2) are not mutually exclusive, and that some conduct might come under either section." United States v. Universal Trade and Industries, Inc., 695 F.2d 1151, 1154 n.3 (9th Cir. 19833). Such appears to be the case in the present circumstances.

Subsection B prohibits receipt of remuneration "in return for purchasing, . . . ordering or arranging for or recommending purchasing . . . or ordering any good, . . . or item for which payment may be made . . . under this subchapter . . . ." The described surgeon's conduct involves both purchasing of lenses directly from the manufacturer and ordering, or arranging for, or recommending the purchasing or ordering of, the lenses by the hospital pharmacy.

Two major defenses are possible. First, with regard to a charge that the remuneration was in exchange for direct purchase of the lenses, one could argue that the payment for this purchase was by the surgeon, not by the Medicare program "under this subchapter" as required to be within the statutory prohibition. Second, with regard to a charge that the remuneration was for recommending the purchase of the lenses by the hospital pharmacy, for which purchase payment was made by the Medicare program, one could argue that the remuneration was paid for the direct lens purchase by the surgeon, not the recommended resale purchase by the hospital.

The problem with both of these potential defenses is the close link between the sale and resale transactions. Although the initial sale and accompanying remuneration do not involve Medicare funds, they contemplate a second transaction involving the same lenses, the resale to the hospital, for which federal funds are involved. The statutory prohibition speaks of remuneration in return for purchases "for which payment may be made" by Medicare. Furthermore, most courts that have interpreted the term "kickback" in the Medicare fraud statute have given it a broad definition that would include the illegality of manufacturer payments to surgeons for purchasing and implanting the company's lenses. See case discussion in Part I.

C. Payments to Investigators

A related issue involves the legality of payments by manufacturers to lens investigators. Both the Food and Drug Administration (which administers the intraocular lens studies) and the Health care Financing Administration (which administers Medicare reimbursement) have held informally that study sponsors can provide reasonable compensation to surgeon investigators for their special services in conducting clinical studies. Under the current phase of lens investigations, an implant surgeon who agrees to conduct "core" studies of intraocular lenses, by undertaking additional examination, testing, reporting and other efforts beyond what is necessary for normal patient care, can be paid reasonable compensation by the manufacturer sponsoring the study. The surgeon should make sure that the investigation agreement with the study sponsor is specific as to precisely what services are to be performed and what compensation is to be paid. If the compensation is unreasonably large, FDA might consider the investigator's judgment biased. This same analysis would probably argue for liablity if the physician receives funds for serving as a "core investigator" in an investigation that is unnecessary of unnecessarily prolonged merely for the purpose of providing a vehicle for extra physician compensation. Under FDA's investigational requirements, studies may not be unnecessarily prolonged. Obviously, if the physician has no way of knowing whether the study is being unnecessarily prolonged, there may be a valid defense; but "studied naivete" is unlikely to shield a professional eye surgeon where he has reason to know, or could easily learn, that participation in a clinical investigation is designed merely to facilitate additional investigator compensation.

Furthermore, should little be required in a clinical study of the surgeon investigator beyond normal patient care, HCFA might consider any payment as in essence a discount, rebate or bonus that must be reflected in Medicare claims.

In this regard, the criminal statutory language excludes

> any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.

If a surgeon is paid by a manufacturer without performing any significant services, an agreement characterizing the payments as, for example, compensation for a surgeon's record-keeping and reporting services as an "adjunct" investigator in the FDA-controlled intraocular lens studies, probably would not be sufficient to avoid the statutory criminal provisions governing treatment of discounts, rebates and bonuses.

IV. Prospective Reimbursement System for Hospitals

In the Social Security Amendments of 1983 (Pub. L. 98-21), Congress established a Medicare prospective payment system for reimbursement of hospital inpatient services. Under the system, hospitals are reimbursed a single fixed payment for each inpatient case based upon 467 separate disgnostic-related groups, one of which, DRG-39, applies to "lens procedures" (cataract surgery). The fixed payment is established according to a formula which takes into account urban and regional differences, outlier payments, medical education costs and other factors. The system is phased in over three years - it will not apply fully until after October, 1986. The effect of the prospective payment system is that a hospital receives a single fixed payment for all of the expenses for an inpatient cataract procedure - operating room, recovery room, patient room, nursing care, pharmaceuticals and, most significantly for this inquiry, the intraocular lens used in the cataract procedure if one is used and is supplied by the hospital. The prospective reimbursement system does not apply to cataract surgery performed on an outpatient basis.

There have been no official pronouncements by HCFA as to the relationship of the Medicare Antifraud provisions to the new prospective payment system generally or with respect to intraocular lens reimbursement.

One might argue that the Antifraud provisions do not apply at all to lenses reimbursed under prospective payment and that therefore discounts, rebates or bonuses in connection with lenses reimbursed under DRG-39 are not illegal under any circumstances. Supporting this argument would be two factors. First, the Antifraud provisions were passed by Congress well before prospective payment; there is no apparent relationship between the two Medicare features; and Congress should have defined a relationship if it intended one. Second, by its nature prospective reimbursement encourages hospitals to seek the lowest price for purchased items such as intraocular lenses and includes reimbursement for lenses in the single fixed payment for a DRG-39 cataract procedure. The hospital has no incentive to receive unreported sales inducements; and Medicare is not hurt by such inducements even if made to physicians for lenses purchased by hospitals. The argument, essentially, is that under prospective reimbursement, otherwise illegal sales inducements simply do not matter.

The countervailing argument is that the Antifraud provision language is very broad. Congress did not specifically exempt the prospective payment system from the Antifraud provisions. And there is a potential harm to Medicare when inducements are made to physicians for lenses purchased by hospitals and reimbursed under DRG-39. The harm is that "overutilization" of Medicare might thereby be encouraged.

This overutilization argument has been stressed by HCFA officials in the Medicare Fraud and Abuse Section in informal interpretations. Those officials feel that the Antifraud provisions do absolutely apply to prospective reimbursement.

However that argument is eventually resolved, two additional factors must be considered by an implant surgeon in considering whether to accept intraocular lens discounts, rebates or bonuses in connection with lens purchases by hospitals for use with inpatient cataract surgery reimbursed under the prospective payment system.

First, DRGs are not yet fully implemented and will not be until after October, 1986. That means that at present, to the extent that hospital reimbursement for inpatient surgery is effected under the original Medicare program, the Antifraud provisions unequivocally apply. Second, it is important to remember that the Antifraud provisions carry criminal penalties - one takes liberties in interpreting this law only at considerable risk.

Finally, of course, it is noted again that DRGs do not affect any Medicare reimbursement for outpatient cataract surgery. It is likely that a majority of this surgery is performed presently on an outpatient basis. The Medicare Antifraud provisions are fully applicable to that surgery as discussed throughout this memorandum.

CONCLUSION

The conclusions stated in this memo are strengthened in view of continuing and heightened scrutiny by Congress and various federal agencies regarding Medicare reimbursement. We must emphasize our warnings regarding the illegality of discounts, rebates and bonuses on intraocular lenses that are not disclosed and passed on by physicians to Medicare reimbursers.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN INTRA-OCULAR
IMPLANT SOCIETY,
118 San Vincente Boulevard
Suite 208
Brentwood, CA 90049
(213) 395-3937

Plaintiff,

v.

MARGARET M. HECKLER,
Secretary
United States Department of
Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
(202) 245-7000

and

CAROLYNE K. DAVIS,
Administrator
Health Care Financing
Administration
United States Department of
Health and Human Services
700 East High Rise Building
6401 Security Boulevard
Baltimore, Maryland 21235
(301) 594-7914

Defendants.

85-1928

Civil Action No. ____

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Plaintiff American Intra-Ocular Implant Society ("AIOIS"), by its attorneys, for its complaint against defendants Margaret M. Heckler and Carolyne K. Davis states:

Nature of Action

1. AIOIS, a professional society of ophthalmologists, brings this action because Defendants, who are responsible for administering the federal Medicare health insurance program, have failed to observe the rulemaking procedures of the Peer Review Improvement Act of 1982 and the Administrative Procedure Act. Defendants have caused Peer Review Organizations ("PROs") to establish and utilize arbitrary and capricious quotas, criteria, and procedures, varying from state to state, which restrict admissions to hospitals when needed by patients undergoing cataract surgery covered by the Medicare program. AIOIS asks that Defendants be required to terminate use of these quotas, criteria, and procedures and to adopt substantive rules and regulations affecting hospital admission for cataract surgery only through public notice, comment, and hearing, as required by law.

Jurisdiction and Venue

2. The Court has jurisdiction of this action pursuant to 28 U.S.C. §§ 1331, 1361, 2201, and 2202.

3. Venue lies in this Court pursuant to 28 U.S.C. § 1391(e) and 5 U.S.C. § 703.

Parties

4. AIOIS is a national professional society of more than 4,000 ophthalmologists (physician eye surgeons) who perform cataract surgery. Cataract is a condition of the

eye in which the natural crystalline lens becomes clouded and impairs vision. Surgical removal of the lens is the only treatment for cataracts. Vision correction is then usually achieved through surgical implantation of an intraocular lens - a tiny plastic prostheses that replaces the natural lens. Cataract surgery is performed in both in-patient and out-patient settings, depending upon the medical and ocular needs of patients.

5. Defendant Margaret M. Heckler (the "Secretary"), named in her official capacity, is Secretary of the United States Department of Health and Human Services ("DHHS") and has statutory responsibility for administration of the Social Security Act, including the Medicare and PRO programs.

6. Defendant Carolyne K. Davis (the "Administrator"), named in her official capacity, is Administrator of the Health Care Financing Administration ("HCFA"), a division of DHHS, and has delegated responsibility for administering portions of the Social Security Act, including the Medicare and PRO programs.

Defendants' Unlawful Acts

7. The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act, Pub. L. 97-248, 42 U.S.C. § 1320c) authorized the Secretary, pursuant to the Act or "under regulations of the Secretary promulgated to carry out the provisions of the Act" (42

U.S.C. § 1320c(3)(a)(8)), to utilize Peer Review Organizations in administering the federal health insurance program for the elderly and disabled established by the Medicare Act, 42 U.S.C. § 1395 et seq. PROs review claims for Medicare reimbursement of medical services, including cataract surgery, to determine whether the services are reasonable and necessary and performed in the most appropriate setting. A PRO is a private organization, ordinarily composed of local medical practitioners, and ordinarily having purview over an entire state.

8. Defendants have, both by direction to PROs and by failure to direct PROs, permitted and encouraged arbitrary and capricious PRO quotas on hospital admissions for cataract surgery covered by the Medicare program, arbitrary and capricious PRO criteria for cataract surgery admissions, and arbitrary and capricious PRO procedures for review of planned or completed cataract surgery. As a result, PROs have adopted - without medical, practical or financial bases - irrational restrictions on in-patient cataract surgery. These restrictions constitute directly and indirectly the exercise of supervision and control over the practice of medicine and the manner in which medical services are provided, all in violation of the Medicare Act, 42 U.S.C. § 1395.

9. The restrictions on in-patient cataract surgery have been adopted and implemented by Defendants through PROs

without notice, comment, hearing, or other opportunity for public involvement as intended by Congress in the Peer Review Improvement Act and in the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, and by DHHS in its own regulations, 36 Fed. Reg. 2532 (1971). Defendants have abdicated their statutory obligation to administer the Medicare and PRO programs by delegating uncircumscribed decision-making authority to privately-run PROs. Defendants have not directed through substantive rules and regulations how PROs should carry out their responsibilities with respect to in-patient cataract surgery. Defendants have not lawfully adopted substantive rules and regulations for evaluating the reasonableness of such activities of PROs. Defendants have not undertaken enforcement actions to terminate the arbitrary and capricious activities of PROs in restricting in-patient cataract surgery. In contrast, Defendants have promulgated rules and regulations concerning many other aspects of the PRO program that are no more substantive than the quotas, criteria, and procedures restricting in-patient cataract surgery.

10. Defendants' failure to direct PROs in carrying out their responsibilities with respect to in-patient cataract surgery, and the resulting arbitrary and capricious nature of PRO quotas, criteria, and procedures restricting that surgery, have caused irreparable injury to AIOIS and its members for which they have no adequate remedy at law.

11. On November 8, 1984, AIOIS filed a Petition for Institution of Rulemaking Procedures to Implement the Peer Review Improvement Act of 1982. A copy of the AIOIS Petition is attached as Exhibit A.

12. On May 2, 1985, the Administrator denied the AIOIS Petition. A copy of the Administrator's denial is attached as Exhibit B.

Prayer for Relief

WHEREFORE, AIOIS respectfully requests that:

1. The Court declare that Defendants' failure to institute rulemaking concerning PRO activities affecting in-patient cataract surgery violates the rights of AIOIS and its members under the Peer Review Improvement Act, the APA, and DHHS regulations, and is arbitrary and capricious, an abuse of discretion, and not otherwise in accordance with law.

2. The Court declare that the arbitrary and capricious quotas, criteria, and procedures restricting in-patient cataract surgery that have been established and utilized by PROs acting under Defendants' authority and control are null and void and constitute directly and indirectly the exercise of illegal supervision and control over the practice of medicine and the manner in which medical services are provided.

3. The Court declare that Defendants' denial of the AIOIS Petition for Institution of Rulemaking Procedures to

Implement the Peer Review Improvement Act of 1982 was arbitrary and capricious, an abuse of discretion, and not otherwise in accordance with law.

4. The Court enjoin Defendants, and PROs acting under Defendants' authority and control, from establishment or utilization of any quotas, criteria, or procedures restricting in-patient cataract surgery without public notice, comment, or hearing.

5. The Court compel, by issuance of a writ of mandamus, Defendants to promulgate forthwith any and all quotas, criteria, or procedures implementing the Peer Review Improvement Act in accordance with § 1320c-3(a)(8) of the Act, the APA, and Defendants' own regulations.

6. The Court enjoin establishment or utilization of any future quotas, criteria, or procedures restricting in-patient cataract surgery unless and until Defendants have issued substantive rules and regulations following public notice, comment, and hearing in accordance with the Peer Review Improvement Act, the APA, and Defendants' own regulations.

7. The Court award AIOIS its costs and reasonable attorney's fees.

8. The Court award such other and further relief as the Court may deem just and appropriate.

Respectfully submitted,

AMERICAN INTRA-OCULAR
IMPLANT SOCIETY

By
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One of its attorneys

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Dated: June 12, 1985

NOV 9 1984
3:05 P.M.

BEFORE THE UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN SERVICES

PETITION OF THE AMERICAN INTRA-OCULAR IMPLANT SOCIETY FOR INSTITUTION OF RULEMAKING PROCEDURES TO IMPLEMENT THE PEER REVIEW IMPROVEMENT ACT OF 1982

TO: The Honorable Margaret M. Heckler, Secretary of Health and Human Services

The American Intra-Ocular Implant Society ("AIOIS"), on its own behalf, on behalf of its 3,500 member eye surgeons, and on behalf of the cataract patients served by its members, petitions the Secretary of Health and Human Services (the "Secretary") to institute rulemaking procedures required by the Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act, Pub. L. 97-248, 42 U.S.C. § 1320c) and the Administrative Procedure Act ("APA"), 5 U.S.C. § 553. For the reasons set forth below, AIOIS respectfully submits that present "targeting" of Medicare-reimbursable procedures for special review or reduction through the Peer Review Organization ("PRO") program is substantively and procedurally improper and must be accomplished through notice-and-comment rulemaking procedures pursuant to 5 U.S.C. § 553(b) and (c).[1]

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[1] To the extent that the October 10, 1984, Petition of the American Hospital Association for Promulgation of Regulations Implementing the Peer Review Improvement Act of 1982 concerns issues that affect AIOIS, its members, and its members' patients, AIOIS joins in that Petition and incorporates it and the supporting Memorandum of Law by reference in this Petition by AIOIS.

EXHIBIT A

Expedited consideration of this petition is requested.

I. The interests of AIOIS are directly and substantially affected by recent actions of PROs in "targeting" cataract procedures for special review and reduction.

AIOIS has been a strong and effective advocate of patients' interest, cost effectiveness and innovation in eye care and the surgical treatment of cataracts.

AIOIS helped achieve a Congressional compromise which assured the broad availability in investigational settings of intraocular lenses ("IOLs") through the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §520g(1)(3)(D)(iii)). IOLs are tiny plastic lenses surgically implanted at the time of cataract removal or later to replace the natural crystalline lens and restore vision without heavy cataract spectacles or contact lenses. Following this legislation, AIOIS worked closely with the Food and Drug Administration to design the present investigational study of intraocular lenses--the largest study of any health care product in history--and to assure patient protection through informed consent and other mechanisms.

AIOIS has for nearly a decade been at the forefront of professional communication and education among eye surgeons. It has been instrumental in promulgating scientific information on improved surgical techniques such as phakoemulsification for cataract removal and efficient surgical settings such as outpatient and ambulatory surgery center ("ASC") cataract removal.

Due in large part to AIOIS efforts, the overwhelming majority of cataract surgery throughout the United States is performed today using modern techniques with reduced patient trauma and improved results, using IOLs that are safe and effective, and using outpatient or ASC settings.

Despite the vast improvement in the safety, efficacy, and efficiency of cataract surgery in recent years, Peer Review Organizations have begun to implement burdensome review procedures and arbitrary numerical limits upon inpatient cataract surgery that will make its benefits less available under the medicare program to those elderly who need the surgery.

PROs established under the 1982 legislation are private organizations, ordinarily composed of local medical practitioners and ordinarily having purview over an entire state, which contract with the Secretary to review medicare-reimbursed procedures to assure that they are necessary, of adequate quality, and performed in appropriate settings (i.e., inpatient, outpatient, ASC) and to make determinations on medicare reimbursement. 42 U.S.C. 1320c-1-3.

PROs have singled out cataract surgery procedures, when performed on an inpatient basis, for reduction according to what are, effectively, quotas for inpatient cataract surgery although PROs euphemistically call them "targets."[2] And practices of PROs have included substantial additional requirements that the eye surgeon request and obtain advance approval for inpatient cataract surgery and specially document the need for a hospital admission before the patient's medicare claim can be processed.[3]

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[2] For example, the Florida PRO has undertaken to
(Footnote continued)

These quotas and "red tape" are inappropriate and unnecessary. They were implemented in violation of the law.

Eye surgeons have no financial incentive to perform cataract surgery on an inpatient basis versus an outpatient basis or vice versa. Their substantive concern about the new PRO quotas and red tape relates exclusively to what is best for patients.

The purpose of cataract extraction is to restore functional vision for the patient. The ultimate decision regarding cataract surgery is mutually agreed upon by the patient and the eye surgeon. The manner in which the surgery is to be performed, the type of anesthesia, and the setting for the surgery are also decided with the aim of making the patient comfortable and relaxed during the

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(Footnote continued)

reduce hospital admissions for cataract surgery by 90% (51,064 procedures) over two years; in California, the reduction is to be 40% (27,544 procedures); in New Mexico, the reduction is to be 15% (337 procedures).

[3] In New Mexico, for example, every proposed inpatient cataract procedure is subject to the requirement that the eye surgeon obtain permission in advance from the PRO for the hospital admission. Other PROs, such as in Florida, require extensive documentation by the surgeon of the reasons for selection of the inpatient setting instead of an outpatient or ASC setting.

procedure and in the immediate postoperative period. Although there is a trend favoring outpatient surgery in hospitals or use of ambulatory surgery centers, there are situations and definite indications for inpatient procedures:

1. When an adequate outpatient facility or ASC does not exist in a particular area, inpatient surgery must obviously be performed.

2. An elderly patient with a complex medical history, frequently using multiple medications, requires close monitoring of his/her medical condition. Coordinating the medical and ophthalmic care of the patient preoperatively, intraoperatively, and postoperatively is most readily performed in the inpatient hospital setting.

3. Inability of the patient to travel to and from the eye surgeon's office for immediate postoperative care is obviated by inpatient surgery.

4. Patients having general anesthesia for cataract surgery require preoperative evaluation and postoperative monitoring. This again may be more successfully performed when the patient has been admitted to the hospital.

5. Patients undergoing combined surgery--for example, cataract extraction and glaucoma surgery, cataract extraction with corneal transplantation, and cataract extraction with vitrectomy--would often benefit from the postoperative care afforded by hospitalization.

In short, the decision by the eye surgeon and patient together as to whether hospital admission is best, from both medical and practical points of view, is a subtle and complicated one.

PROs have targeted inpatient cataract procedures for arbitrary reductions on the inaccurate premise that too many such procedures are performed too early. For example, the New Mexico PRO asserts, on the basis of unidentified information, that "[i]t is of general concern among ophthalmologists that thesre [sic] are too many instances in which lens extration [sic] takes place prematurely."[4/] This general statement is simply untrue. The concept of "prematurity" as applied to cataracts is obsolete. While delay in cataract treatment of vision-impaired patients was justified a decade ago when the prevailing treatment was more traumatic and risky, treatment using the relatively more benign and effective modern procedures and IOLs does not ordinarily have to be deferred for any patient who has suffered substantial vision impairment. What degree of vision impairment is substantial enough to justify surgery varies. For example, immediate surgery may be indicated for a patient whose occupation requires excellent vision even

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[4/] Contract No. 500-084-0524 for Operations of Utilization and Quality Control Peer Review Organization for the State of New Mexico between HHS/HCFA and the New Mexico Medical Reveiw Association, Admission Objective #2a in Attachment I to Article III (effective date August 1, 1984).

though retired cataract patients with equivalent vision may best delay their surgery. This delicate decision, requiring close consultation between physician and patient, cannot effectively or reliably be made by a PRO official. AIOIS is not aware of any evidence even suggesting that a substantial number of IOL procedures are performed on patients whose vision has not been substantially impaired by cataracts. Truly "unnecessary" surgeries, if they exist, should be eliminated completely.

For PROs to unilaterally declare that in their areas some percentage of inpatient cataract surgery decisions by eye surgeons and their patients are incorrect, or that the decision-making can possibly be enhanced by the intrusion of PRO officials, is substantively erroneous. It contradicts the clear mandates of the medicare law to avoid interference with the physician-patient relationship and respect the need to maintain quality medical care. In particular, the situation came about through violation of federal rulemaking requirements.

II. Cataract procedures may not be targeted for special reductions or review without compliance with the APA.

Congress required PROs to perform their functions only as may be required by the Peer Review Improvement Act of 1982 "or under regulations of the Secretary promulgated to carry out the provisions" of that Act. 42 U.S.C. § 1320c-3(a)(8) (emphasis added). Congress' insistence that the Secretary proceed through rulemaking procedures that give affected parties an opportunity to be heard reflected

Congress' belief that the PRO program's objectives "can be achieved through an effective partnership between the Government and the private sector."[5/] The kind of partnership that Congress envisioned was not limited to a formalistic opportunity for the private sector to object to PRO rules after their unilateral adoption or to make claim denial challenges on a one-by-one basis. Congress intended a free exchange of information and ideas _before_ such rules were adopted.

Compliance with notice-and-comment rulemaking procedures is necessary to achieve the purposes of the APA. The APA seeks "to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." _National Association of Home Health Agencies v. Schweiker_, 690 F.2d 932 (D.C. Cir. 1982) (quoting _Batterton v. Marshall_, 648 F.2d 694, 703 (D.C. Cir. 1980)), _cert. denied_, 459 U.S. 1205 (1983). "Broad delegations of rulemaking authority from the Congress were intended to be tempered by assuring a degree of due process for those to be governed by the rule." _American Academy of Pediatrics v. Heckler_, 561 F. Supp. 395, 398 (D.D.C. 1983). The need for effective public oversight is even greater where governmental functions have been

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[5/] S. Rep. No. 97-494 on H.R. 4961, Tax Equity and Fiscal Responsibility Act of 1982, 97th Cong., 2d Sess. at 41 (1982), _reprinted in_ [1982] U.S. Code Cong. & Adm. News 781, 817.

delegated to a private entity like a PRO. PROs are twice removed from elected accountable officials because PRO administrators and directors, who implement these "targets" and procedures and who decide whether or not governmental benefits under a statutory federal program will be paid, are unelected individuals accountable only to unelected governmental employees. They may also be in competition to provide services to patients in their areas. To allow such entities and individuals to operate without clear and well-founded rules, or with rules into which the public has had no meaningful input, would violate the fundamental objectives of the APA.[6/]

Although the Secretary has promulgated regulations concerning other, no more substantive aspects of the PRO program, no regulations have been promulgated concerning the critical issues of whether and how to "target" specific services for special review or reduction. Any criteria that PROs have used to regulate particular procedures or settings are simply not addressed by any regulation and have been adopted and used without any opportunity for public comment.

[6/] The requirements of the APA apply to all federal agencies. To the extent that PROs are responsible for the selection and implementation of special rules for targeted procedures, PROs clearly function as federal agencies within the meaning of 5 U.S.C. § 551(1). Congress did not intend to permit federal agencies like HCFA to avoid the requirements of the APA by making open-ended, uncircumscribed delegations of governmental authority through contracts with non-governmental entities.

Procedures and settings could be, and in AIOIS's view have been, limited by quotas on the basis of conjecture and speculation. Compliance with the procedures of the APA would substantially enhance the quality of the decision-making process by ensuring "that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions." National Association of Home Health Agencies v. Schweiker, 690 F.2d at 932 (quoting Guardian Federal Savings & Loan Association v. Federal Savings & Loan Insurance Corp., 589 F.2d 658, 662 (D.C. Cir. 1978)).

AIOIS of course does not object to employing special scrutiny for procedures which have been determined, on the basis of reasonable, reliable, objective data, to be subject to abuse. But incorrect quotas on specific procedures or settings undermines the objectives of the PRO program in a number of ways. For example, implementation of preadmission and preprocedure review requirements imposes substantial and expensive burdens on physicians as well as patients and can interfere with timely delivery of needed medical services. Incorrect quotas can cause PROs to focus their limited resources on procedures which are provided in an appropriate and economical manner and thereby to give insufficient attention to procedures where substantial cost savings could be achieved without restricting the provision of necessary and appropriate medical care.

Under any reasonable definition, "targeting" procedures for special scrutiny constitutes substantive rulemaking within the meaning of 5 U.S.C. § 551(4).[7] Singling out certain procedures necessarily has real and substantial consequences. Preadmission and preprocedure review requirements impose substantial paperwork and bureaucratic burdens. Establishment of unrealistic and unjustified quotas for reduction of targeted procedures has an inherently chilling effect on performance of those procedures.

These "targets" are not merely interpretative rules within the meaning of § 553(b)(A) of the APA, which exempts "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from rulemaking procedures. To transform a general congressional injunction to eliminate unnecessary procedures and avoid inappropriate settings into a specific requirement to reduce a particular procedure by a particular percentage requires more than "interpretation." Decisions to "target" certain procedures for special review and reduction were not the result of "interpretation" of a federal statute; rather, they were the product wholly of the entity that picked the targets. In addition, as described above, these quotas have a direct and substantial impact on the providers of these services and their patients. Moreover, the § 553(b)(A) exemption does not apply "when notice or hearing is required by statute," 4 U.S.C. § 553(b), and 42 U.S.C. § 1320c-3(a)(8) expressly requires implementation of the PRO program by regulation.

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[7] This subsection defines a "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy . . . ."

Rules specifying certain procedures for reduction and review are not exempt from the APA as "a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts" within the meaning of 5 U.S.C. § 553(a)(2). Even assuming that this exemption were otherwise applicable, the Secretary waived this exemption and required "all agencies and offices of the Department which issue rules and regulations relating to public property, loans, grants, benefits, or contracts . . . to utilize the public participation procedures of the APA." 36 Fed. Reg. 2532 (1971). This waiver is binding on the Secretary. *Daniel Freeman Memorial Hospital v. Schweiker*, 656 F.2d 473, 476 n.2 (9th Cir. 1981); *Humana of South Carolina v. Califano*, 590 F.2d 1070, 1084 (D.C. Cir. 1978); *Washington Hospital Center v. Heckler*, 581 F. Supp. 195, 198 (D.D.C. 1984). In any event, this exemption is inapplicable because Congress explicitly required the Secretary to promulgate rules and regulations concerning these matters. 42 U.S.C. § 1320c-3(a)(8).

No other exemption from the rulemaking requirements of the APA is even arguably relevant. The "good cause" exemption in § 553(b)(B) requires the agency to incorporate the finding, as well as the reasons, that notice and public procedures are "impracticable, unnecessary, or contrary to the public interest." The Secretary has not complied with these requirements. All such exemptions are to be "narrowly construed . . . and only reluctantly countenanced," Environmental Defense Fund v. Gorsuch, 713 F.2d 802, 816 (D.C. Cir. 1983), and there is no basis to invoke them in connection with these aspects of the PRO program.

III. Relief

For the reasons set forth above, AIOIS respectfully requests the Secretary to promulgate forthwith for notice and comment, or require PROs to promulgate for notice and comment, rules and regulations that provide as follows:

(1) any "targeting" of any medical service for special review or reduction, and any procedures or standards for such review or reduction, by any PRO must be based on valid, reliable, and objective data and methodology demonstrating that this service is provided unnecessarily or inappropriately in a sufficient percentage of cases to justify such procedures or standards;

(2) no PRO may impose any numerical quota or other restriction on any reimbursable procedure unless the basis for any such quota or other restriction has been publicly disclosed and the public has been afforded an appropriate opportunity to comment.

(3) PROs must grant all claims for reimbursement of services that are medically necessary and appropriate and

are provided at reasonable cost, regardless of whether approval of the claim would cause the PRO to exceed the number of claims which the PRO has otherwise decided to reimburse;

(4) PROs may not consider, in connection with review of any individual claim for reimbursement, whether approval would prevent the PRO from meeting any objective for reduction of medicare reimbursement; and

(5) PROs may not, directly or indirectly, exercise any supervision or control over the practice of medicine or in the manner in which medical services are provided.

AIOIS further respectfully requests that the Secretary give expedited consideration to this Petition because PROs are at this time operating according to rules and regulations that include targets for review and reduction of certain procedures and that have not been promulgated in accordance with 42 U.S.C. § 1320c-3(a)(8) and the APA and because PROs are scheduled to commence review of Medicare reimbursement claims for hospitals on November 15, 1984.

AIOIS further respectfully requests that the Secretary promptly hold a hearing to consider this Petition and the issues that it raises.

Respectfully submitted,

AMERICAN INTRA-OCULAR
IMPLANT SOCIETY

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

MAY 2 1985

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Re: Petition for Rulemaking of the American Intra-Ocular Implant Society

Dear Mr. Jacobs:

This is in response to the November 8, 1984 Petition for Rulemaking of the American Intra-Ocular Implant Society (AIIS) requesting the promulgation of certain regulations governing the Utilization and Quality Control Peer Review Organization (PRO) program. As discussed below, all appropriate rulemaking processes have been completed and comprehensive regulations governing the implementation of the PRO program have been published. The issues AIIS has itself identified in its petition as warranting rulemaking procedures deal with specific negotiated elements of individual PRO contracts for which rulemaking is not required or appropriate. Other issues for which rulemaking was requested in a petition of the American Hospital Association, (incorporated by AIIS in footnote 1 of its petition) have either now been addressed in regulations or similarly involve negotiated elements of individual contracts. The bases for these conclusions are set forth in detail below.

I. HHS Has Correctly Promulgated All Regulations Required For Implementation of the PRO Program

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1983 (TEFRA), Pub. L. 97-248) amended the Social Security Act (Act) replacing the Professional Standards Review Organization (PSRO) program with the PRO program. Since the passage of TEFRA, HHS has actively sought and obtained public participation in the implementation of the PRO program through extensive rulemaking proceedings. This process has resulted in the promulgation of comprehensive regulations dealing with all aspects of the PRO program. The public and provider communities have taken an active role participating in the development of these regulations.

1. Guidelines for Area Designations and the Definition of Eligible Organizations.

A notice of proposed rulemaking was published on August 15, 1983 (48 F.R. 36970). Approximately 100 comments on the proposed rule were received from medical societies, PSROs, State governments, advocacy groups, individual physicians, other private individuals, and hospital associations. These comments were considered and responded to in the final regulation published on February 27, 1984 (49 F.R. 7202). This regulation provides guidelines for the designation of PRO areas and details the qualifications necessary for an organization to become a PRO.

2. Notice of PRO Area Designations.

On August 15, 1983, a proposed notice was published to designate PRO areas throughout the country. Over 200 public comments were received from PSROs, private medical review institutions, hospitals, medical centers, State agencies, and hospital associations, including comments from the AHA. After consideration of these comments, the final notice designating the actual PRO areas was published on February 27, 1984 (49 F.R. 7209).

3. PRO Assumption of Review Responsibilities

On July 17, 1984, a notice of proposed rulemaking was published (49 F.R. 29026) that described in detail the review functions a PRO must perform and the relationships that will be established among PROs, fiscal intermediaries and carriers, providers, practitioners, and beneficiaries when a PRO assumes review responsibilities. It also described the relationship that should exist between PROs and State Medicaid agencies that contract with PROs to perform review. Seventy-eight comments on the proposed regulation were received from PSROs, hospitals, business groups, national medical organizations, and hospital associations. These comments were considered, appropriate changes were made, and the final regulations were published on April 17, 1985 (50 FR 15312).

4. Confidentiality of PRO Information.

A notice of proposed rulemaking was published on April 16, 1984, governing the acquisition, protection, and disclosure of information by a PRO (49 F.R. 14977). Over 160 letters of comment were received from hospitals, state and national medical associations, peer review organizations, members of Congress, other interested parties and hospital associations. These comments were reviewed, necessary changes were made, and the final rule was published on April 17, 1985 (50 F.R. 15347).

5. PRO Hearings and Appeals Regulations

Proposed regulations governing appeals from PRO determinations were published on July 17, 1984 (49 F.R. 29041). Forty seven comments were received from PSROs, hospital associations, hospitals, a state agency concerned with the elderly, an association representing the elderly, legal advocates for the elderly, fiscal intermediaries, and organizations representing physicians, nurses, and medical colleges. These comments were considered, appropriate changes were made, and the final regulations were published on April 17, 1985 (50 F.R. 15364).

6. PRO Sanctions.

On April 18, 1984, a proposed rule was published concerning the obligations of health care practitioners and others who provide health care services to Medicare beneficiaries and the sanctions that may be imposed for violations of the obligations (49 F.R. 15233). Fifty-two comments were received, including those from individuals, hospitals, medical societies, hospital associations, other professional organizations, and PSROs. The comments were considered, appropriate changes made, and the final rule was published on April 17, 1985 (50 F.R. 15335).

In addition to these specific PRO regulations, other provisions governing PRO review have been included in regulations promulgated for the Medicare Prospective Payment System (e.g. 42 C.F.R. §§412.44, 412.82.) These were first published on September 1, 1983 as interim rules (48 F.R. 39752). Amendments were published in final rules on January 3, 1984 (49 F.R. 234) and August 31, 1984 (49 F.R. 34728). 1/

Furthermore, the PRO program officials took an additional unusual step that was not legally required in order to receive further guidance from the public and providers. They requested comments concerning the Scope of Work that was to be used in the Request for Proposals (RFP) to solicit proposals for PRO contracts in the 46 States subject to Medicare's Prospective Payment System for hospital reimbursement. 48 F.R. 39160 (August 9, 1983), 49 F.R. 9959 (March 16, 1984). Sixty-nine comments on the Scope of Work were received from peer review organizations, national medical organizations, individual physicians, organizations representing the elderly, and hospital associations, including the AHA. Although clearly no obligation existed to make changes based on the comments, the comments received from the public were carefully considered and the Scope of Work was revised as appropriate.

As a result of this extensive process, a comprehensive framework has been established within which the PRO program is being implemented. Those interested in the PRO program have been given every opportunity to comment

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1/ Also see corrections published October 19, 1983 (48 F.R. 48467), January 4, 1984 (49 F.R. 408), and June 1, 1984 (49 F.R. 23010) and the recent recodification of these regulations published March 29, 1985. (50 F.R. 1270). The amendments of August 31, 1984 had been preceded by a notice of proposed rulemaking published on July 3, 1984 (49 F.R. 27422).

upon all aspects of the program. As evidenced by the discussions of the comments contained in the preambles to the regulations and the texts of the regulations themselves, it is clear that these comments were carefully considered. In response to these comments, many changes were made in the final rules. These regulations, the PRO statute, and other relevant portions of the Medicare statute and regulations, taken together, provide a comprehensive, detailed description of the substantive requirements necessary for implementation of the PRO program. As a result, we believe that no further rulemaking is required.

II. Rulemaking with Regard to Negotiated Review Objectives Is Not Required By the Administrative Procedure Act.

The issue for which rulemaking is requested in AIIS' petition concerns negotiated objectives contained in the individual contract between a PRO and the Health Care Financing Administration (HCFA). 2/ Specifically, AIIS' petition claims that negotiated, contract-specific goals for reductions in unnecessary inpatient admissions for cataract surgery should be subjected to rulemaking procedures. Subjecting such objectives to rulemaking would be impracticable, and is contrary to statutory requirements for individually negotiated contracts.

Although the PRO statute and regulations provide the overall description of how the program is to be implemented, Congress has unequivocally required HHS to negotiate specific requirements for review with each PRO:

> "the Secretary shall include in the contract negotiated objectives against which the organization's performance will be judged, and negotiated specifications for use of regional norms, or modifications thereof based on national norms, for performing review under the contract." (Emphasis added). Section 1153(c)(7) of the Act (42 U.S.C. 1320c-2(c)(7).

The Secretary shall enter into a contract with a PRO only if:

> "such organization and the Secretary have negotiated a proposed contract which the Secretary determines will be carried out by such organization in a manner consistent with the efficient and effective administration of this part." Section 1153(b)(1) of the Act (42 U.S.C. 1320c-2(b)(1)).

2/ The Secretary has delegated the responsibility for administering Part B of Title XI of the Social Security Act to the Administrator of HCFA (49 FR 35248, September 6, 1984.)

The PRO statute provides further that:

> "the organization [PRO] shall, after consultation with the Secretary, determine the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order to most effectively carry out the purposes of this part, exercise review authority under the contract. The organization shall notify the Secretary periodically with respect to such determinations." Section 1154(a)(4) of the Act. (42 U.S.C. 1320c-3(a)(4)).

The Secretary has been given extraordinarily broad authority to implement the program through the individual PRO contracts:

> "Contracting authority of the Secretary under this section may be carried out without regard to any provision of law relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the purposes of this part. The Secretary may use differing contracting methods with respect to different geographical areas." Section 1153(e) of the Act. (42 U.S.C. 1320c-2(e)).

The entire thrust of these provisions is to give the Secretary and the PROs as much flexibility as possible in implementing the PRO program through negotiated individual contracts. This was done in order to ensure that the PRO program would be more effective and efficient than the prior PSRO program. A significant innovation of the PRO Act was to change the administrative structure for medical peer review under Medicare from a grant system to a system of negotiated, performance-based contracts. The new approach can be expected to increase cost-effectiveness and the contractor's responsiveness to achieving program goals.

The basic requirements for all PROs are set forth in the statute and the regulations. No substantive PRO responsibilities have been included in the PRO contracts that are not in the statute or regulations. The individually negotiated PRO contracts merely indicate how those responsibilities will be performed in a particular PRO area. Each contract is different depending upon local medical practice patterns and other conditions prevailing in a PRO area.

Requiring rulemaking with regard to individual objectives or targets submitted by each PRO for negotiation is particularly inappropriate. The objectives submitted by the PROs, the specific way in which they will be met, the appropriate goals for a given area, etc., are not in any way substantive rules of general applicability. They are merely proposals by a private organization that form a basis for negotiating those objectives and specifications which are to be included in a specific contract as required by §1153(c)(7). They reflect the varying needs for medical review in fifty-four different PRO areas and the appropriate standards through which the PRO intends to meet them. Through a series of individual contract negotiations, HCFA and the PROs have reached agreement with regard to the actual terms of each contract. To require that a PRO's submissions and the give-and-take of negotiations be subjected to rulemaking is not only totally impracticable but also contrary to the statutory requirements for individual, flexible, negotiated contracts (specifically, "negotiated objectives").

The negotiated objectives described in AIIS' petition constitute an amplification of clear requirements of provisions in the statute and regulations. Section 1154(a)(1) of the Social Security Act provides that PROs shall conduct review, "subject to the terms of the contract," to determine whether -

...

> (C) in case ... services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

The regulations, at 42 C.F.R. §466.70(c), (50 FR 15330, date) further provide that a PRO must determine, "in accordance with the terms of its contract" -

> (3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health cafe facility of a different type;"

The targets referred to in AIIS' petition 3/ reflect one example of the specific ways in which individual PROs (which have familiarity with the needs and practices of their given areas) propose to meet the above requirements of the statute and regulations. The extent to which these targets vary by PRO area demonstrates the inappropriateness of subjecting such details to rulemaking of general applicability. In some PRO areas, there is no target

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3/ See footnote 3 of AIIS' petition.

established for reduction in unnecessary inpatient admissions for cataract extractions. As reflected in AIIS' petition, however, in other PRO areas, targets for reduction vary from 15% to 90% over two years. These goals reflect local experts' familiarity with the local extent of unnecessary inpatient admissions.

These "targets" represent flexible goals, not rigid quotas. To the extent inpatient admissions are found to be justified under Medicare coverage criteria, they will be covered even if they exceed the target figure for a given area. The targets thus do not constitute arbitrary cutoff points for coverage, but merely represent expert predictions as to the level of reduction in unnecessary inpatient admissions that the local PRO believes to be a reasonable contract objective in its area. There would be no authority to withhold payment with respect to any item or service that meets Medicare coverage criteria, and the targets clearly do not purport to do so. Thus, if given inpatient admissions are medically appropriate for the reasons stated in AIIS' petition, for example, and meet other applicable requirements, Medicare payment will be made. The targets do not change this.

Initially, the "negotiated objectives" or targets to which AIIS objects reflect the *predictions* of a *prospective* PRO, based on its knowledge of local conditions and how they compare with medical practice patterns elsewhere, of the likely or probable extent of unnecessary inpatient admissions in its area. These targets are used to evaluate the contract proposals of prospective PROs, and when a PRO contract is awarded and the targets are included among the contract terms, the targets are used to evaluate the PRO's performances. If actual program experience reveals that the targets at issue are unrealistic or unattainable (*i.e.*, inpatient admissions in excess of the targets consistently prove to be justified), then adjustments in the target figures will be made, and the PRO would face no penalty provided the modifications are valid and submitted in a timely and appropriate manner. These targets would yield to Medicare coverage requirements and actual experience.

The need for flexibility in the establishment of selection criteria and individual contract provisions to carry out the requirements of a program otherwise governed by statute and regulations has been approved by the courts. *Grassetti* v. *Weinberger*, 408 F. Supp. 142, 153 (N.D. Cal. 1976) (review of NIH research proposals); *Lemberos* v. *Laurel Racecourse, Inc.*, 489 F. Supp. 1376, 1389 (D. Md. 1980) (regulations governing race tracks). To require greater specificity in the PRO regulations would "restrict the ability of [the] administrative agency to promulgate appropriate regulations to meet the varied situations with which they must deal." *Id.*, *citing*, *Brenner* v. *Occupational Safety and Health Review Commission*, 505 F.2d 869, 872 (10th Cir. 1974).

III. The Further Issues Raised In the American Hospital Association's Petition Have Now Been Addressed In The Regulations, or Similarly Involve Negotiated Contract Objectives

AIIA's petition has incorporated, in footnote 1., an October 10, 1984 petition for rulemaking by the American Hospital Association (AHA). The AHA's petition has requested rulemaking with regard to certain issues specified on pages 16-20 of its Petition for Rulemaking. As a result of the extensive rulemaking proceedings described in section I. above, the issues listed in AHA's Petition have now been dealt with through rulemaking, in particular Items A, C, D, J, L, M, N, O, P, Q, R, S, and T. Each of these items, and the relevant provisions in the statute and regulations, are addressed below. As discussed below, the remaining items for which AHA's petition requests rulemaking (Items B, E, F, G, H, I, and K) concern negotiated objectives contained in individual contracts and are not subject to rulemaking requirements.

Item A requests regulations requiring that all PRO contract objectives conform to the criteria set forth below.

Item A.(1) requests that all PRO contract objectives be based on the quality of care and access, i.e., medical considerations, rather than on financial considerations.

Response

Sections 1154 and 1866(a)(1)(F) of the Act and regulations at 42 C.F.R. 466.70(c) limit PRO review to determinations concerning the medical necessity, quality, and level of care provided. These provisions are incorporated by reference in each PRO contract. Determinations based on financial considerations are not authorized by the PRO statute or the regulations.

Item A.(2) requests that all objectives reflect local needs and circumstances, including the age and gender of the population served, local standards of medical practice, and the range of services available in individual communities.

Item A.(4) requests that all objectives take into account the non-medical factors that affect utilization patterns such as the ability of patients to travel to receive services and the availability of support for patients at home.

Response to Items A.(2) and A.(4)

Section 1152(2) of the Act states that PROs will review the pattern of quality of care in an area of medical practice using criteria which define acceptable and adequate practice. Local needs and circumstances, the range of services available in a community, or non-medical factors such as described in the petition which may not be addressed in the criteria could be considered by local reviewing physicians in determining the appropriateness of medical care for those services covered by Medicare.

Item A.(3) requests that all objectives be based on identified problems and address unnecessary or inappropriate utilization.

Response

Sections 1153(c)(7), 1154(a)(1), 1154(a)(4), 1866(a)(1)(F) and 1886(f)(2) of the Act and regulations at Subpart C of 42 C.F.R. Part 412 and Subparts A and C of 42 C.F.R. Part 466 set forth the requirements for PRO review, including the review of identified problems, unnecessary utilization, and utilization patterns. Furthermore, the individual PRO contract objectives are based on identified problems. In order to fulfill the requirements of the contract, the PRO must undertake activities to address these identified problems. Discussions of specific issues concerning these aspects of PRO review are also included in the preambles to the PRO regulations and the preambles to the PPS regulations published on September 1, 1983 (48 F.R. 39752, 39785-39792) and on January 3, 1984 (49 F.R. 234, 278, 282-288).

Item C requests a regulation that limits the application of PRO contract objectives to PRO performance not to hospital practices.

Response

Promulgation of such a provision is unnecessary because it is clear from Section 1153 of the Act and regulations at 42 C.F.R. 462.107 that the contractual relationship that exists is solely between the PRO and HHS. Pursuant to Section 1153(c) of the Act, 42 C.F.R. 462.105(c), and 42 C.F.R. 466.70, the fulfillment of contract objectives is solely the responsibility of the PROs. Hospitals are not parties to the contract and they are not otherwise responsible for performance under the contract.

Item D requests a regulation that states that PRO contract objectives are not an appropriate basis for determining the necessity or appropriateness of admissions or claims in particular cases.

Response

Promulgation of such a provision is unnecessary because Sections 1154(a)(1) and (2) and 1866(a)(1)(F) of the Act and regulations at 42 C.F.R. 466.70(c) clearly limit the scope of PRO review to medical considerations. Furthermore, PRO determinations must be based on local, regional, and national standards of care (Sections 1152(2), 1153(c)(7) and 1154(a)(6) of the Act; 42 C.F.R. 466.100). PRO contracts reiterate that PRO denials must be based on medical considerations, and not solely on the basis of criteria reviews. If appropriateness of care cannot be confirmed by the nurse reviewer, the claim is always referred for a medical opinion by a local reviewing physician.

Item J requests a regulation setting forth criteria and procedures to be used in conducting pre-admission and pre-procedure reviews, day and cost outlier reviews, and DRG validations.

Response

Requirements for the conduct of all aspects of review, including pre-admission and pre-procedure reviews, day and cost outlier review, and DRG validations appear at Subparts C and F of 42 C.F.R. Part 412; Subparts A and C of 42 C.F.R. Part 466, and Subpart B of Part 473. The individual criteria and procedures used by PROs will vary with each organization and, as discussed below, are negotiated elements in the PRO's contract with the Secretary. Details concerning the actual conduct of review in a specific facility must be discussed with the facility (42 C.F.R. §466.76) and will be a part of the agreement between the facility and the PRO as required by 42 C.F.R. §466.78(a).

Item L requests rulemaking with regard to the requirement that no more than 24 hours notice be given to providers prior to requests for medical records for purposes of conducting DRG validation.

Response

Section 1866(a)(1)(F) of the Act and regulations at 42 C.F.R. 466.70(c) require PROs to conduct DRG validations. Sections 1154(a)(7)(C) and 1154(a)(9) of the Act require PROs to examine, collect, and maintain information, including hospital records as necessary to carry out their responsibilities under the Act. Section 1156(a)(3) requires health care providers to maintain evidence, as required by the PROs, of the medical necessity and quality of services they provide. No requirement for advance notice is included in the statute; however, HCFA has determined that it will provide such notice. This is a matter of internal procedure between HHS and the PROs and does not impose any new substantive requirement on a hospital. Therefore, rulemaking is not required.

Item M requests rulemaking with regard to the requirement that hospitals, not PROs, bear the cost of copying and transmitting medical records to the PRO.

Response

Regulations at 42 C.F.R. 466.78(b)(2) set forth the requirements for copying and transmitting records. They require a hospital to photocopy and deliver requested records to the PRO without charge to the PRO. In its comments on the Conduct of Review regulations the AHA objected to this requirement. This comment was considered but was not accepted. The reasons why it was not accepted are described in the preamble to the Assumption of Review Regulations (50 F.R. 15315). This issue is also discussed in the preambles to the Sanction Regulations (50 F.R. 15337-15338) the Confidentiality Regulations (50 F.R. 15355), and the Reconsideration and Appeals Regulations (50 F.R. 15368).

Item N requests rulemaking with regard to a system by which PROs would retroactively recompute denial rates at hospitals, based on the outcome of reconsiderations and appeals.

Response

The Reconsideration and Appeals Regulations (50 F.R. 15364) describe the actions that are to be taken on the basis of the outcome of reconsiderations and appeals. The regulations do not require PROs to recompute denial rates on the basis of these appeals because administratively this would be extremely difficult to do. In computing a denial rate for a quarter, however, hospitals will be given "credit" for previous denials which are reversed during a review quarter. Such cases will be subtracted from denials made in the review quarter. Thus, they will act to lower denial rates for the quarter in which they were reversed.

Item O requests rulemaking with regard to the circumstances and manner in which providers may lose a "favorable presumption" when the 2.5% inappropriate admissions level is exceeded.

Item P requests rulemaking with regard to the effect of a PRO's rebuttal of the waiver of liability on a hospital's ability to bill for services.

Response to Items O and P

Proposed regulations concerning the waiver of liability provisions were published in the Federal Register on February 12, 1985 (50 F.R. 5787). These items are more appropriately addressed in the context of these new rulemaking proceedings.

Item Q requests rulemaking with regard to the basis for the automatic rebuttal of the "favorable presumption" in cases of pre-admission denials.

Response

When a pre-admission denial is made, the provider clearly has knowledge that payment will not be made for certain services. As a result of this knowledge, there could not be a determination that excluded services would be paid pursuant to 42 C.F.R. §§405.330-405.332.

Item R requests rulemaking with regard to the basis, data, and methodology used in establishing the PRO performance evaluation system and the severity index.

Response

Rulemaking with regard to PRO performance evaluation is not possible because the methods by which overall PRO activities might be evaluated have not yet been developed. Ongoing monitoring of PROs is being conducted pursuant to the specific negotiated terms of each contract. The severity index was developed by physicians based on their professional judgment and was used merely as a tool to evaluate the quality of care objectives. The severity index was made available for public comment along with the draft PRO Scope of Work.

Item S requests a regulation that requires that reconsideration reviews be conducted by objective and appropriately qualified individuals.

Response

The issue of the qualifications of reconsideration reviewers is dealt with at page 15368 of the Preamble to the Reconsideration and Appeals Regulations. The qualifications required of reviewers are set forth at 42 C.F.R. 473.28.

Item T requests rulemaking with regard to the factual, legal, and policy basis for the prohibition against provider representation of beneficiaries in claims appeals.

Response

This request is addressed in the Preamble to the Reconsideration and Appeals Regulations at 50 F.R. 15369 (April 17, 1985).

Items U and V request rulemaking with regard to any other substantive rules contained in transmittals, the February 29, 1984 Request for Proposal, the PRO contracts with HCFA, Directive No. 2 dated August 3, 1984 or any other further substantive PRO program rules that may be implemented in the future.

Response

As discussed above, all substantive requirements for PRO review are set forth in the Medicare and PRO statutes and regulations. The PRO Transmittals and Directives merely reiterate and further interpret these requirements. They do not impose obligations that are not already in the statute and regulations. As a result, they are not subject to the rulemaking requirements of the Administrative Procedure Act. Columbus Community Hospital v. Califano, 614 F.2d 181,187 (8th Cir. 1980) (Medicare reimbursement manual); American Medical International Inc. v. Secretary of HEW, 466 F. Supp. 605, 616 (D.D.C. 1979) (Medicare reimbursement manual).

Items B, E, F, G, H, I, and K

The remaining items for which rulemaking is requested in AHA's petition 4/ deal with negotiated objectives contained in individual contracts between a PRO and HCFA. As discussed above in section II., rulemaking is not required or appropriate in this area because these negotiated objectives are not substantive rules of general applicability. 5 U.S.C. 552(a)(1)(D).

For the reasons set forth above, the Petition for Rulemaking is denied.

Sincerely,

Carolyne K Davis

Carolyne K. Davis, PH.D.

4/ For example, the petition (Item B) requests rulemaking with regard to the basis for and methodologies used in determining the admission and quality objectives contained in the PRO contracts. Sections 1153(a)(1)(B) and 1866(a)(1)(F) of the Act and regulations at 42 C.F.R. 466.70(c) clearly require PROs to conduct review of the necessity of hospital admissions and the quality of care provided. How they perform this review, however, depends upon the local circumstances in the specific PRO area. As part of the contracting process, PROs submitted individual proposals describing how the admissions practices they selected were to be reviewed and how identified issues regarding quality that they identified were to be addressed. Each one of the PRO proposals contained supporting baseline data and descriptions of proposed methodologies that obviously varied greatly from objective to objective and from area to area. Each resulting objective and the methodology for achieving it is unique to that objective and to the particular PRO area. Therefore, there is no one body of data or any methodology or set of methodologies on which comment could be sought. This is true as well with regard to the remaining items for which rulemaking is requested (Items E, F, G, H, I, and K).

Mr. PEPPER. Thank you very much, Doctor. We will come back for questioning a little later.

We are very honored and pleased today to have with us the Honorable Dave Durenberger, U.S. Senator from the State of Iowa—I mean Minnesota. Senator, I am sorry.

Senator Durenberger was originally scheduled to appear with a later panel dealing with the Federal and IOL industry response, but due to a previous commitment he will have to leave soon, and therefore we will hear his testimony at this time. Please proceed, Senator.

STATEMENT OF HON. DAVE DURENBERGER, CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON FINANCE, U.S. SENATE

Senator DURENBERGER. Them's fighting words where I come from.

Mr. PEPPER. They are both good States.

He is the chairman of the Senate Subcommittee on Health, U.S. Senate Committee on Finance, a very important position.

We are pleased to have you, Senator. We welcome your statement.

Senator DURENBERGER. Thank you very much for giving me the opportunity to be here, and in particular the opportunity to appear before you, not only because the whole world and the country is aware of your commitment to health care for the elderly, but because you do something about it. And over on the Senate side, let me tell you, we all call you "Senator Pepper," and very much enjoy working with you on these issues.

We are all concerned about guaranteeing adequate health care for older Americans. We are now calling a large number of people in this country "chronologically gifted people" now, as a compliment to them. I am doing that, since I was eligible this year for the first time to join AARP. I am beginning to feel more and more a part of your generation, Mr. Chairman.

Over the past week, we have seen the way in which health care issues come into vogue very quickly, but very temporarily. We all are deluged with accounts of the President's illness. The American public today knows more about colon cancer than they did a week ago. That big, full-page advertisement in the Washington Post today—somebody has a way to detect it—it makes it all worthwhile. I suspect next week it will be off the front pages, or maybe in a couple of weeks. We will forget about our own symptoms. We will forget about going and having a checkup ourselves. It will sort of be back to business as usual.

Because that is part of America, it has made it difficult for those of us who deal in health care policy to do what many would consider to be the right thing. Instead, we are often fighting only the high cost of health care when really, I think, our motivation—and you would agree with me, Mr. Chairman—our motivation is still accessibility; it is still quality. It is not just how do you keep costs down.

But the costs are a reality. We know that the high cost of health care in this country has threatened the bankruptcy of the Medicare Program. We know that it is that drive that may have pushed us at times away from taking meaningful action. But, thankfully, the evidence is now coming in that our efforts to contain health care costs at the same time we maintain accessibility and quality are beginning to pay off in protecting the Medicare fund for the foreseeable future. So, it is incumbent upon the Congress, through hearings like this, to continue to push for reforms where they are needed before the problems become crises.

You could not have picked better examples of costly abuses in health care than the overcharges for intraocular lenses and outpatient cataract surgery. These types of abuses within the Medicare Program are not anecdotal. They are indications of basic changes that need to be made within the system.

In a sense, our ability to smoke out these problems is testimony to the reforms we have already made in Medicare financing. Now that we have stopped simply paying the bills without thought to cost control and moved instead to fixed fee prospective payment, some of the frauds and the scams that were there all the time can no longer hide behind the ledgers and the invoices.

There is a bill sitting, Mr. Chairman, on my desk right now ready to be introduced next week that addresses the concerns that you are addressing here today. In line with the principles of fixed price payment I have always advocated, the bill would set a fixed prospective payment for Medicare outpatient surgery at the same rate as that paid to ambulatory surgery centers for the same procedure. That rate could be no higher than the prospective DRG rate paid for inpatient treatment, and it would be updated annually.

When a procedure becomes less expensive to perform, we will pay less for it. That outpatient rate would include the cost of all prosthetic devices and lab work. In other words, your local intraocular lens salesman will be forced to offer you the best price for his product rather than to spend Medicare money to send you to Bermuda.

The bill would also take specific steps to ensure quality in outpatient care and encourage the growth of ambulatory surgical centers.

Mr. Chairman, I planned this bill as a step toward a more comprehensive approach to prospective payment under Medicare. Earlier this year, I spoke to a group of ophthalmologists. After the speech, an Australian doctor asked me why, in his country, cataract surgery pays him only $170, and in the United States it pays as much as $2,500. Well, I don't want any ophthalmologists to worry that we are going to get our payment standards down to the Australian level, but we will have to develop fee schedules or incentives that establish reasonable prices in this country.

In 2 or 3 years, we should be paying one lump sum for this treatment, including the physician's fee. It is important—we can't do that immediately, but it is important that we keep the physician as the focus on the treatment. Because it is the doctor who decides, first, whether to perform the surgery or not; second, where is this particular patient going to get the best surgery and under what circumstances. We must give that physician the right kinds of incentives to operate only when necessary and at the facility with the best price.

I just heard what the doctor to my left said about PROs, and I am as upset by some of the ways we set standards as he. I just want to accent that there is a way to do peer review to ensure quality and necessity without using it to bar access for the judgment that belongs there between the physician and the patient.

The American citizen is not conditioned to be a smart health care consumer. We aren't used to asking whether our doctor could have gotten this lens cheaper or whether we are getting tests that are necessary. What we are used to is getting our health care on a platter from the Government or our employee health plan or whatever with no questions asked.

But, Mr. Chairman, we know those days are over. Today's health care philosophy has to be: Give me what I need, do it right, and charge me what it costs, no more—because the "more" comes out of my pocket or that of my children.

As you know, Mr. Chairman, the biggest health care consumer of all is the Federal Government. We buy health care for 31 million Americans under Medicare and Medicaid, and it is our responsibility to stand in front of the crowd and say we will not be ripped off, not any more.

Mr. Chairman, I thank you for this opportunity to appear before you today. And, again, I commend your efforts to fight health care fraud and abuse against our elderly and against our Government.

Mr. PEPPER. Senator, it is very meaningful to me and to the people of America to hear such a strong and able voice as yours speaking out for what is justice in this critical matter. I hope it will not be lost upon those who have been the perpetrators of the wrongs of which we are speaking here today.

The Congress is concerned about this matter. We will be forced to take action, as you have indicated you are prepared to do and we are prepared to do. Doctors and the industry may be assured we will do it in close cooperation and confederation, to try to find a way to protect the public interest from the kinds of abuse that we have had to be told about here today.

It is a great privilege to work with you. You may be assured of our full and whole cooperation over here with your fine efforts in the Senate.

We are most grateful, as I told you, for your being kind enough to come here today for our hearings.

Ms. Oakar.

Ms. OAKAR. Thank you. I have no questions.

I think you said it very well, Senator, what the issue here is today. Actually, I have been kind of a student of what the Finance Health Subcommittee is doing in my capacity as a member of this committee and being interested in the whole subject of health care. I think you are doing some very innovative things.

I think the thing I like the most about you, as a good Democrat saying that, is that you are not afraid to look at things and say we have had enough of the status quo, let's go on to new, progressive ideas that cannot only save money but achieve quality health care.

I hope we can work together on some ideas, and I really applaud the kind of leadership you are providing on the Senate side in that area.

Senator DURENBERGER. Thank you. I appreciate that.

Mr. **Pepper**. Thank you again, Senator. We are very grateful for your being with us.

The next witness on our panel is Dr. Douglas Williamson. He is accompanied by Dr. David McIntyre, secretary-treasurer of the Outpatient Ophthalmic Surgery Society. He is from my State.

Dr. Williamson, we are pleased to have you. If he wishes to say something, Dr. McIntyre may speak also.

STATEMENT OF DOUGLAS WILLIAMSON, M.D.

Dr. **Williamson**. Mr. Chairman, members of the subcommittee, I am Dr. Douglas Williamson of Venice, FL. Fifteen years ago, I opened the first surgery facility in the United States that was specifically designed for outpatient ophthalmic surgery. I appear before you today as president of the Outpatient Ophthalmic Surgery Society, a professional medical specialty organization representing over 900 ophthalmologists dedicated to the conduct of safe, effective, and cost-effective surgery in the outpatient surgical settings.

As a professional medical specialty organization, we share this committee's, this panel's, and the public's outrage at marketing and reimbursement practices which drain the Medicare budget, potentially taint the professional judgment of the physician vis-a-vis his choice of surgical devices, and place a cloud over the entire ophthalmology profession. We hope to work with the committee, its staff, the Health Care Financing Administration, the office of the inspector general, and industry in developing and implementing rational and equitable reforms in the marketing and reimbursement of IOL's.

Mr. Chairman, your committee staff has asked the Society to address an issue which is perhaps peripheral to your concerns regarding IOL fraud and abuse. The ultimate goal of this committee and of the Congress is to ensure that Medicare beneficiaries receive the highest quality care at the lowest possible cost. Curbing IOL fraud and abuse will doubtless conserve precious health dollars.

However, we believe that this committee should take a comprehensive look at the potential cost savings embodied in the conduct of cataract surgery on an ambulatory basis—savings which potentially amount to hundreds of millions of dollars per year. It is appropriate to discuss this issue at this hearing because Medicare is footing virtually the entire national cataract bill, a bill which is increasing annually as patients demand a procedure which results in rapid visual restoration without significant discomfort. We believe that an important response to the question of skyrocketing health care costs is to promote the utilization of freestanding ambulatory surgical facilities. There are a number of factors fueling the developing of freestanding ambulatory surgical facilities—economics, quality of care, and governmental pressures.

With regard to economics, quite simply, ambulatory surgery costs one-third to one-half as much as surgery conducted within the hospital environment—both on an inpatient and outpatient basis. Insurance carriers and employers throughout the country have recognized the potential for health cost savings by providing reimbursement incentives to physicians and patients to promote the conduct of surgery within the freestanding environments.

Ambulatory surgical facilities also offer the opportunity for the provision of the highest quality surgical care. Medicare conditions of participation, State licensure, and private accreditation efforts assure a quality of care that is comparable to, or exceeds, the hospital setting. The procedures conducted within ASC's are limited to those which can be safely and effectively performed within the ambulatory environment. The patient is able to more quickly resume normal activities with less disruption of family life. Moreover, the patient is having his surgery conducted without the exposure to contagious disease and infection incident to hospital care. Surgical care in the freestanding ambulatory facility also minimizes the anxiety which elderly patients experience with regard to hospitalization and surgery; studies suggest that freestanding units outperform hospitals in friendliness of staff, attention to a patient's needs, and pleasantness of environment.

Moreover, surgical, preoperative, and postoperative care attain optimum levels since the surgeon has access to his own equipment and to his own employees who are specially trained in ophthalmology. From the standpoint of the physician's productivity, he is able to schedule a greater number of medically appropriate procedures, since he is performing surgery in an environment free of being bumped from the surgical schedule and free of the significant turnover time between operations in the hospital outpatient department.

Governmental pressures have also intensified the migration of surgical services from the hospital inpatient to outpatient arenas. The Medicare prospective payment system has ratcheted down inpatient reimbursement, and private carriers are following. Peer review organizations have contracted with HCFA to reduce admissions in certain high-utilization DRG categories; indeed, 35 States' PRO's have applied some form of limitation on the conduct of cataract surgery on a hospital inpatient basis. As we will discuss later, it appears that Congress may, rightfully, place limits on hospital outpatient reimbursement as well.

Perhaps the greatest boon to the conduct of surgery in the freestanding surgical environment is the Medicare Ambulatory Surgical Center Program, implemented in September 1982. A facility which is certified for Medicare reimbursement receives two basic benefits. The facility receives a facility fee for each of the 100 or so surgical procedures approved by the Medicare Program; this facility fee ranges from $231 to $504, the latter being the reimbursement rate for a cataract extraction and intraocular lens implantation. Moreover, the surgeon who conducts a Medicare-approved procedure in a Medicare-certified ASC and who accepts Medicare assignment receives 100 percent, rather than 80 percent, of his reasonable charge. Under these circumstances, the patient is not liable for any coinsurance amounts with respect to the facility fee or the surgeon's charge. In other words, under the Medicare ASC program, the elderly beneficiary, who may likely be living on a fixed income, can have his surgery conducted and incur no out-of-pocket expense. In sum, the total cost of the cataract procedure is as follows: to the Government, $504, plus the cost of IOL; to the beneficiary, no cost—if the physician accepts assignment.

Let us contrast these levels with the reimbursement amounts paid to hospitals. On an inpatient basis, hospitals are reimbursed for their facility costs at a rate of approximately $1,300 to $1,600 under DRG 39. However, as noted above, the activities of peer review organizations and changes in technology and surgical technique have led to a substantial migration of services away from the hospital inpatient operating room.

It is estimated that approximately 70 percent of the over 800,000 cataract procedures performed this year will be conducted in hospital outpatient departments. The Medicare prospective payment system does not apply to the hospital outpatient setting. Medicare continues to pay on the basis of 80 percent of the lower of reasonable costs or charges, with the patient responsible for the difference in the 20 percent of coinsurance. One would expect that, since there is no room and board component to the same-day procedure, hospital charges for cataract surgery on an outpatient basis would range between the freestanding ASC rate of $504, plus IOL, and the inpatient DRG rate of about $1,400.

However, charge information which we have collected throughout the country demonstrates that charges for the facility component of cataract cases performed in hospital outpatient departments substantially exceeds the amounts paid to ASC's, and indeed, often exceeds the inpatient DRG payment.

The Outpatient Ophthalmic Surgery Society asked its membership to collect information regarding the charges of hospital outpatient charges for cataract surgery. We received information on the charges of hundreds of hospitals in over 20 States. We identified these hospitals' charges through at least one of the following means: One, media advertising in which the hospital identified its charge for cataract surgery; two, actual hospital invoices; and three, telephone calls to hospital staff requesting charge information.

Mr. Chairman, we have turned over to your staff all information and documentation received as a result of our survey. The results are astounding. Hospital outpatient charges for cataract surgery range from just under $1,000 to well over $4,000, with an apparent average of about $2,000.

If we assume some reasonable correlation between hospital outpatient department charges and reimbursable costs, it is apparent that hospital outpatient departments are being reimbursed for the facility costs at rates which are significantly higher than the rates paid to ambulatory surgical centers, and in some instances, even higher than rates paid for services rendered to hospital inpatients under DRG 39.

In some areas where ophthalmic ASC's have been established, hospitals have aggressively marketed their services by advertising that they will waive the 20-percent coinsurance for Medicare beneficiaries; some of these advertisements are posted in this room. It is no wonder that a hospital can afford to take out one page ads and waive the patient's coinsurance when it is receiving facility reimbursement amounting to two, three, or four times higher than the reimbursement to the freestanding ASC in the community.

These discrepancies in reimbursement lead us to conclude that Medicare is paying hospitals, on the average, hundreds of dollars more for the cataract procedure performed in the hospital outpatient department than in the ASC. In times of fiscal austerity, when the Government should be promoting fair and healthy competition among providers, the reimbursement differentials for cataract surgery and other surgical procedures simply cannot be justified.

To address these inequities, as Senator Durenberger stated, he is going to introduce legislation, the concepts of which we hope will be embraced by this committee in the recommendation to the House of Representatives.

His concepts and his goals that he outlined are the identical goals of our organization, to provide the best possible care for our patients at the lowest possible cost. We appreciate the opportunity of appearing before you today and pledge to cooperate in the development of the appropriate legislative remedies to the aforementioned problems.

[The prepared statement of Dr. Williamson follows:]

PREPARED STATEMENT OF DOUGLAS WILLIAMSON, M.D., PRESIDENT, OUTPATIENT OPHTHALMIC SURGERY SOCIETY, VENICE, FLORIDA

I am Dr. Douglas Williamson of Venice, Florida. Fifteen years ago, I opened the first surgery facility in the United States that was specifically designed for outpatient ophthalmic surgery. I appear before you today as President of the Outpatient Ophthalmic Surgery Society, a professional medical specialty organization representing over 600 ophthalmologists dedicated to the conduct of safe, effective, and cost-effective surgery in the outpatient surgical settings.

As a professional medical specialty organization, we share this Committee's, this panel's, and the public's outrage at marketing and reimbursement practices which drain the Medicare budget, potentially taint the professional judgment of the physician vis-a-vis his choice of surgical devices, and place a cloud over the entire ophthalmology profession. We hope to work with the Committee, its staff, the Health Care Financing Administration, the Office of the Inspector General, and industry in developing and implementing rational and equitable reforms in the marketing and reimbursement of IOLs.

Mr. Chairman, your Committee staff has asked the Society to address an issue which is perhaps peripheral to your concerns regarding IOL fraud and abuse. The ultimate goal of this Committee and of the Congress is to ensure that Medicare beneficiaries receive the highest quality care at the lowest possible cost. Curbing IOL fraud and abuse will doubtless conserve precious health dollars.

However, we believe that this Committee should take a comprehensive look at the potential cost savings embodied in the conduct of cataract surgery on an ambulatory basis -- savings which potentially amount to hundreds of millions of dollars per year. It is appropriate to discuss this issue at this hearing because Medicare is footing virtually the entire national cataract bill, a bill which is increasing annually as patients demand a procedure which results in rapid visual restoration without significant discomfort. We believe that an important response to the question of skyrocketing health care costs is to promote the utilization of freestanding ambulatory surgical facilities. There are a number of factors fueling the development of freestanding ambulatory surgical facilities -- economics, quality of care, and governmental pressures.

With regard to economics, quite simply, ambulatory surgery costs one-third to one-half as much as surgery conducted within the hospital environment -- both on an inpatient and outpatient basis. Insurance carriers and employers throughout the country have recognized the potential for health cost savings by providing reimbursement incentives to physicians and patients to promote the conduct of surgery within the freestanding environments.

Ambulatory surgical facilities also offer the opportunity for the provision of the highest quality surgical care. Medicare conditions of participation, state licensure, and private accreditation efforts assure a quality of care that is comparable to, or exceeds, the hospital setting. The procedures conducted within ASCs are limited to those which can be safely and effectively performed within the ambulatory environment. The patient is able to more quickly resume normal activities with less disruption of family life. Moreover, the patient is having his surgery conducted without the exposure to contagious disease and infection incident to hospital care. Surgical care in the freestanding ambulatory facility also minimizes the anxiety which elderly patients experience with regard to hospitalization and surgery; studies suggest that freestanding units outperform hospitals in friendliness of staff, attention to a patient's needs, and pleasantness of environment.

Moreover, surgical, preoperative, and postoperative care attain optimum levels since the surgeon has access to his own equipment and to his own employees who are specially trained in ophthalmology. From the standpoint of the physician's productivity, he is able to schedule a greater number of medically appropriate procedures, since he is performing surgery in an environment free of being "bumped" from the surgical schedule and free of the significant turn-over time between operations in the hospital outpatient department.

Governmental pressures have also intensified the migration of surgical services from the hospital inpatient to outpatient arenas. The Medicare prospective payment system has ratcheted down inpatient reimbursement, and private carriers are following. Peer review organizations have contracted with HCFA to reduce admissions in certain high-utilization DRG categories; indeed, thirty five states' PROs have applied some form of limitation on the conduct of cataract surgery on a hospital inpatient basis. As we will discuss later, it appears that Congress may, rightfully, place limits on hospital outpatient reimbursement as well.

Perhaps the greatest boon to the conduct of surgery in the freestanding surgical environment is the Medicare ambulatory surgical center program, implemented in September, 1982. A facility which is certified for Medicare reimbursement receives two basic benefits. The facility receives a facility fee for each of the 100 or so surgical procedures approved by the

Medicare program; this facility fee ranges from $231 to $504, the latter being the reimbursement rate for a cataract extraction and intraocular lens implantation. Moreover, the surgeon who conducts a Medicare-approved procedure in a Medicare-certified ASC and who accepts Medicare assignment receives 100%, rather than 80%, of his reasonable charge. Under these circumstances, the patient is not liable for any coinsurance amounts with respect to the facility fee or the surgeon's charge. In other words, under the Medicare ASC program, the elderly beneficiary, who may likely be living on a fixed income, can have his surgery conducted and incur no out-of-pocket expense. In sum, the total cost of the cataract procedure is as follows: to the government, $504, plus the cost of the IOL; to the beneficiary, no cost (if the physician accepts assignment.)

Let us contrast these levels with the reimbursement amounts paid to hospitals.

On an inpatient basis, hospitals are reimbursed for their facility costs at a rate of approximately $1,300 to $1,600 under DRG #39. However, as noted above, the activities of peer review organizations and changes in technology and surgical technique have led to a substantial migration of services away from the hospital inpatient operating room.

It is estimated that approximately 70% of the over 800,000 cataract procedures performed this year will be conducted in hospital outpatient departments. The Medicare prospective payment system does not apply to the hospital outpatient setting. Medicare continues to pay on the basis of 80% of the lower of reasonable costs or charges, with the patient responsible for the difference in the 20% of coinsurance. One would expect that, since there is no room and board component to the same-day procedure, hospital charges for cataract surgery on an outpatient basis would range between the freestanding ASC rate of $504 (plus IOL) and the inpatient DRG rate of about $1,400.

However, charge information which we have collected throughout the country demonstrates that charges for the facility component of cataract cases performed in hospital outpatient departments substantially exceeds the amounts paid to ASCs, and, indeed, often exceeds the inpatient DRG payment.

The Outpatient Ophthalmic Surgery Society asked its membership to collect information regarding the charges of hospital outpatient charges for cataract surgery. We received information on the charges of hundreds of hospitals in over 20 states. We identified these hospitals' charges through at least one of the following means: (1) media advertising in which the hospital identified its charge for cataract surgery; (2) actual hospital invoices; and (3) telephone calls to hospital staff requesting charge information.

Mr. Chairman, we have turned over to your staff all information and documentation received as a result of our survey. The results are astounding. Hospital outpatient charges for cataract surgery range from just under $1,000 to well over $4,000, with an apparent average of about $2,000. If we assume some reasonable corelation between hospital outpatient department charges and reimbursable costs, it is apparent that hospital outpatient departments are being reimbursed for their facility costs at rates which are significantly higher than the rates paid to ambulatory surgical centers, and, in some instances, even higher than rates paid for services rendered to hospital inpatients under DRG #39.

In some areas where ophthalmic ASCs have been established, hospitals have aggressively marketed their services by advertising that they will waive the 20% coinsurance for Medicare beneficiaries; some of these advertisments are posted in this room. It is no wonder that a hospital can afford to waive the patient's coinsurance when it is receiving facility reimbursement amounting to two, three, or four times higher than the reimbursement to the freestanding ASC in the community.

These discrepancies in reimbursement lead us to conclude that Medicare is paying hospitals, on the average, hundreds of dollars more for the cataract procedure performed in the hospital outpatient department than in the ASC. In times of fiscal austerity, when the government should be promoting fair and healthy competition among providers, the reimbursement differentials for cataract surgery and other surgical procedures simply cannot be justified.

There is an alternative, and we would urge this Committee to develop legislation which would rectify this reimbursement anomoly and provide other incentives for the establishment of ambulatory surgical centers, where this nation's citizens can receive the highest quality surgical care of reduced cost. Senator David Durenberger will soon introduce legislation in the Senate which, we would hope, will be embraced by this Committee in its recommendations to the House of Representatives.

- The legislation would "level the playing field" between facility payments made to hospitals and freestanding ambulatory surgical facilities. It would establish a prospective payment mechanism for surgery performed in hospital outpatient departments. Medicare would not pay for any procedure performed in a hospital outpatient surgical facility an amount more than the DRG rate for the same procedure. In addition, for procedures on the ASC procedures list, Medicare would pay the hospital outpatient department an amount equal to the ASC facility rate for that procedure. It may be that hospital outpatient departments incur costs which exceed those of ASCs; however, cost-based reimbursement provides absolutely no incentive for a department to reduce its costs. Hospital outpatient departments and freestanding facilities should be afforded the opportunity of competing for patients on relatively equal footing vis-a-vis facility reimbursement.

o The legislation would require the Health Care Financing Administration to update the facility rates paid to ambulatory surgical centers prior to January 21, 1986, and to adjust these rates at least annually. ASC facility payment rates have not been increased since the ASC program was initiated in 1982. The payment rate for a procedure like cataract extraction, i.e. $504 plus IOL, is probably $100 to $300 lower than the actual costs incurred in conducting the procedure. (It is for this reason that few multi-specialty ASCs even elect to offer cataract surgery services.) For well over two years, HCFA has been promising the ambulatory surgery community that it will conduct a survey of Medicare-participating ASCs to ascertain appropriate facility rates for of covered procedures. As recently as three weeks ago, we were informed by HCFA that payment rates would not likely be updated for another 12 to 18 months. The failure of Medicare to update these rates is clearly stifling the development of ASCs which have proven that they can deliver a broad array of surgical services at significantly lower costs than other providers.

o The legislation would preclude states from discriminating against Medicare-certified ASCs by imposing certificate-of-need, licensure, or other regulatory requirements on Medicare-certified ambulatory surgical centers when such requirements are not imposed on similar entities not seeking to qualify for Medicare reimbursement. In many states, a surgical suite owned and operated in conjunction with a physician's office practice is exempt from CON and licensure requirements as the "private practice of medicine." However, any effort by a surgical suite to qualify for Medicare reimbursement as an ambulatory surgical center often results in the imposition of certificate-of-need and licensure requirements which would not otherwise be applicable. We support provisions which would preclude states from discriminating against Medicare-qualified, physician-sponsored surgical suites.

- The legislation to be offered by Senator Durenberger would modify the methodology used to determine the amount of facility rates paid to ASCs and hospitals by providing that such rates are to include all Medicare-covered services except physicians' services. Under this provision, for example, intraocular lenses and other prosthetic devices provided to surgical patients would not be reimbursed separately under Part B of the Medicare program, but would be paid for as part of an expanded prospectively determined facility rate. Enfolding IOL reimbursement into facility rates would ameliorate a number of the IOL marketing and reimbursement problems discussed in this hearing, since providers would have an incentive to negotiate the best possible price for the IOL of choice and the government would not pay a higher amount for a more expensive lens.

- The legislation would explicitly expand the responsiblity of peer review organizations to include review of ambulatory surgical procedures performed in ASCs and hospital outpatient departments. As a Society dedicated to the conduct of high-quality, medically appropriate cataract surgery, we support PRO review of all surgery conducted in Medicare-certified facilities.

The Outpatient Ophthalmic Surgery Society appreciates the opportunity of appearing before this distinguished body to discuss these issues of vital concern to the health care community. We pledge our assistance in the development and implementation of appropriate reforms governing the marketing and reimbursement of intraocular lenses. Moreover, in the interest of promoting fair competition among providers and reducing health costs to beneficiaries and the Medicare program, we look forward to working with the Committee in equalizing facility reimbursement rates for cataract surgery performed in the various surgical environments.

Mr. PEPPER. Dr. McIntyre.

STATEMENT OF DAVID McINTYRE

Dr. McINTYRE. It is a pleasure to be here and to speak before your committee, Mr. Pepper. Not only have we succeeded in getting a segment of our population how to pronounce ophthalmologist, I believe your subcommittee deserves the credit for having brought astonishing clarity to a complex issue and I compliment you for that.

You have reported your conversation from the chairman at Harvard, I believe it was, that the DRG system is based on diagnostic rather than procedure, a very important factor, and the ASC system, on the other hand, is based on procedures and, therefore, is a very useful system for the reimbursement of the types of therapy we are speaking of.

Second, the inpatient hospital system is quite different from the outpatient hospital, and the ambulatory surgical center system.

You have demonstrated with the DRG system attempting to hold the line on inpatient hospital procedure costs, costs spreading in the hospital has caused the outpatient department cost to rise, so that they now exceed inpatient costs.

We have also discovered privately that this can be a very striking factor. I was called recently from another city in this country with a question. A physician's office was inquiring why, when their local hospital had just certified their own ambulatory surgical center owned by the hospital, certified by Medicare reimbursement, why was the hospital then refusing to do cataract surgery in their new ASC. They were insisting that any cataract should be done as hospital outpatient rather than the hospital-owned ASC.

The answer is here in this room. We have seen also that there is no cost data developed by HCFA regarding ambulatory surgical center costs. The data does not exist.

For 2 years they have been attempting to develop the form on which the data would be gathered and we still have neither the form nor the data.

The DRG system has now obtained data to date on the actual costs of supplying this care on an inpatient basis, and therefore, there is a guideline as to what the procedure actually costs.

It includes within it, of course, the hospital charges for overnight stay, but there is a guideline available to us, and we have seen that the abuse, the total abuse in the implant costs may total in the range of $50 million, whereas the total potential saving and the facility charges which will be in the range of $350,000, a very sizable factor.

Again, my congratulations to you for an immense clarification of this very complex issue, and thank you very much.

Mr. **Pepper**. Doctor, thank you very much.

Our next witness is Dr. James Aquavella of Rochester, NY, and I believe he is accompanied by Dr. Jerome Bettman. We will be pleased to have you proceed.

STATEMENT OF JAMES AQUAVELLA, M.D.

Dr. **Aquavella**. My name is James Aquavella. I am a practicing ophthalmologist from Rochester, NY, associate secretary for health plans for the American Academy of Ophthalmology. I am accompanied by Dr. Jerome Bettman of Woodside, CA, who is chairman of the academy's ethics committee. We are appearing on behalf of the American Academy of Ophthalmology representing more than 13,500 or 90 percent of the physicians who specialize in medical and surgical treatment of the eye. We appreciate very much this opportunity to present the academy's views on intraocular lenses and cataract surgery.

We appreciate your comments this morning recognizing the unique role of cataract surgery in maintaining a level of vision adequate to support the independence of our senior citizens, a truly important factor.

The success rate of cataract surgery and associated new technology has resulted in a large increase in the number of operations over a very short period of time.

This has indeed created some problems which must be addressed vigorously. Any abuse must be eliminated and cannot be allowed to undermine the delivery of this important care.

The academy's leadership is aware of the diverse, competitive marketing arrangements offered by intraocular lens manufacturers. Some are variations on volume, purchasing discounts which appear to be acceptable practice. Others offer various inducements to purchase a particular product and may be suspect.

Still others are schemes which are clearly unethical, if not illegal, involving kickbacks and special favors, and these have been brought before this committee this morning.

The academy strongly supports direct action to eliminate fraud and abuse and urges the prosecution of individuals involved in criminal activity.

To protect the integrity of ophthalmology, the academy has adopted and implemented a code of ethics, the first and only health care organization code of ethics to receive a favorable advisory opinion from the Federal Trade Commission.

An ophthalmologist's clinical judgment and practice must not be affected by economic interest or benefit from it professionally, in the form of related commercial enterprises.

Our code of ethics is enforced through a process which may result in a termination of membership, under certain circumstances the academy may transfer a summary of its action to a law enforcement agency, physical licensing authority or medical quality review board and indeed, Mr. Chairman, over the past 2 years, I have met with representatives of the Government Accounting Office. We have consulted with the office of the inspector general.

We maintain a close liaison and consult frequently with HCFA on these and related issues. Three years ago I also was approached personally by one of these schemes, and my response, of course, your committee was not in session, was to turn it over to Dr. Bettman and his ethics committee and it proceeded along normal channels.

We have attempted to educate our members in these important areas through repeated articles in our newsletter including a detailed review of HCFA guidelines to medicare carriers on pacemaker and IOL rebates.

There is a striking similarity in the two situations. The academy cooperates with HCFA and maintains open communication with the GAO, the inspector general's office and the administrative staff of the White House.

In summary, we condemn fraud, abuse and criminal activity and welcome all efforts to prosecute those engaging in illegal and unethical practices. We will continue to offer our cooperation in maintaining high ethical standards for ophthalmology.

Your committee has identified anomalies in Medicare's payment methodologies relating to inpatient and outpatient cataract surgery.

The combination of the fixed price for inpatient cataract surgery, the lack of price controls on hospital outpatient surgery, and the ambitious goals of the new peer review organizations have resulted in a revolutionary shift to outpatient cataract surgery.

The academy recognized this trend toward outpatient surgery years ago and we have cooperated with HCFA in developing appropriate guidelines. We are very hopeful that HCFA will announce their expanded list of procedures shortly.

Medicare pays for cataract surgery and reimburses for intraocular lenses using different methodologies associated with a variety of settings and providers, and this is the crux of the problem.

As a result, there are documented inconsistencies in billing and payment levels, as well as a great deal of confusion and concern.

For example, for an inpatient procedure a hospital may be losing a portion of the cost of the IOL under the DRG 39 rate. We heard Mr. Smith address that problem.

In the same hospital outpatient department the hospital may receive considerably more than the invoice price of the lens. In a free-standing ambulatory surgical center or when billed by an individual physician, the reimbursement may be equal to, more than, or less than the invoice price of the lens, depending on the vagaries of the system that is in place.

I personally direct a unit comprised of 16 independent-minded ophthalmologists. We utilize six intraocular lens vendors each providing an array of lens designs, powers, sizes, and prices.

I can attest to the logistical difficulties in complying with guidelines in a volatile and competitive market place characterized by frequent price changes, varying discounts, shipping charges and inventory systems.

The academy recommends establishment of a standardized payment methodology for intraocular lens based on net acquisition cost plus a modest handling charge. Such a standard applied throughout the industry would prevent misunderstanding, facilitate monitoring and minimize fraud.

The academy suggests that there should not be extraordinary incentives toward one site of surgery or another. The surgeon should have the option to select the surgical setting based on patient needs.

Cost is an important but secondary factor. We recommend the establishment of ongoing monitoring systems to adjust reimbursement levels, eliminating inequities when they appear, thus avoiding situations which lead to fraud and abuse.

Mr. Chairman, we thank you for this opportunity to express our views. Dr. Bettman and I will be pleased to answer any questions the committee may have.

[The prepared statement and attachments submitted by Dr. Aquavella follow:]

PREPARED STATEMENT OF JAMES AQUAVELLA, M.D., ASSOCIATE SECRETARY FOR HEALTH PLANS, AMERICAN ACADEMY OF OPHTHALMOLOGY, ROCHESTER, NY

My Name is James Aquavella. I am a practicing ophthalmologist from Rochester, NY, and Associate Secretary for Health Plans of the American Academy of Ophthalmology. I am accompanied by Jerome Bettman of Woodside CA, Chairman of the Academy's Ethics Committee. Today, we are appearing on behalf of the American Academy of Ophthalmology, representing more than 13,500 or 90 percent of the physicians who specialize in medical and surgical treatment of the eye. We appreciate the opportunity to present the Academy's views on intraocular lenses (IOLs) and cataract surgery.

The Committee knows how important adequate vision is in maintaining the independence of our senior citizens. Cataracts are a major cause of impaired vision and blindness among the elderly, with an 18 percent prevalence among the 65 to 74 age group, and 45.9 percent prevalence among the 75 to 85 age group. [1] Fortunately, eyesight can be restored in the majority of cataract cases through highly successful modern cataract extraction techniques. The implantation of prosthetic intraocular lens provides superior rehabilitation, often resulting in near normal vision.

The success rate of cataract surgery and associated new technology has resulted in an expansion of the number of operations in recent years, creating a number of problems. These should be addressed vigorously. Any existing abuse must be eliminated and cannot be allowed to undermine the delivery of this important care.

We will address the two broad issues raised by the Committee: (1) alleged fraud, abuse and criminal activities between manufacturers and physicians relating to the purchase of intraocular lenses; and (2) the anomalies associated with recent developments in Medicare payment for cataract surgery. These items are not unrelated. A single, clear reimbursement methodology for intraocular lenses that could be applied throughout the industry would prevent misunderstanding, facilitate monitoring and, consequently, would eliminate most opportunities for fraud.

Intraocular Lens Purchasing Issues

The market for ophthalmic devices is an extremely competitive one, and has become more so in recent years, with the growing number of new products, the pressures of the rapid changes in hospital economics, and the increase in rates of IOL implantation. In 1983, 631,000 IOLs were implanted. [2]

The Academy's leadership is aware of the diverse, competitive selling techniques and arrangements offered by intraocular lens manufacturers. Some are variations on volume purchasing discounts, which appear to be acceptable practices. Others are more complicated, offering various inducements to purchase a particular product, and may be suspect.

And, there are those schemes which are clearly unethical, if not illegal, involving kickbacks, special favors, etc. The Academy strongly supports direct action to eliminate fraud and abuse, and urges the prosecution of those individuals involved in criminal activity.

The Academy has cooperated with government officials in establishing Medicare policies relating to cataract surgery. Internally, we continue to work with our members, providing guidance through our informational channels, and our ethics committee.

In an effort to protect the integrity of ophthalmology, the Academy has adopted and implemented a code of ethics, and established an ethics committee. This code is the first and only health care organization's code of ethics to receive a favorable advisory opinion from the Federal Trade Commission. The code is based on the following ethical principles. (1) Ophthalmological services must be provided with compassion, respect for human dignity, honesty and integrity. (2) Open communication with the patient is essential. Patient confidences must be safeguarded within the constraints of the law. (3) Fees for ophthalmological services must not exploit patients or others who pay for the services. [3]

Our Rules of Ethics, which are enforceable through a process which may result in loss of Academy membership privileges and other sanctions, address the standards of ethical behavior relating to the purchase of ophthalmic devices, as follows. (1) An ophthalmologist must not misrepresent the service that is performed or the charges made for that service. (2) Ophthalmologists should order only those laboratory procedures, optical devices or pharmacological agents that are in the best interest of the patient. Ordering unnecessary procedures or materials for pecuniary gain is unethical. (3) An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally-related commercial enterprises.

These rules were specifically applied in a June, 1984 ethics committee advisory opinion (approved by the Academy's Board of Directors) on the subject of: "Rebates and Other Payments to Ophthalmologists Related to the Purchase of Intraocular Lenses." A copy is appended to our written testimony. The ethics committee concluded: ". . . The psychological reality is that a person cannot always sort out all his/her motives. Medical device manufacturers skillfully combine appeals based on scientific information, personal contact, professional relations, and economic incentives. Therefore an ophthalmologist should guard against unwittingly having his/her clinical judgement colored-by scrupulously avoiding economic arrangements which might affect such judgement. Whenever an ophthalmologist receives any thing of substantial value from a device vendor, simply for ordering its products, there is potential for distortion of his/her clinical judgement, distortion of the doctor/patient relationship, and an ethical conflict."

> ". . . We believe that most difficulties, in this area can be avoided by observing several basic tenets: (1) the ophthalmologist should either decline any payment or other thing of value (including a discount) offered by an intraocular lens vendor, or (2) if appropriate accept it, pass along to the patient (and/or third party payors) the true value of the benefit, and disclose to the patient (or third-party payors) that the true costs will be reflected in the ophthalmologists charges." [4]

The Academy's code of ethics is enforced through a process which may result in a termination of membership, with publication of the action and the ophthalmologist's name. Under certain circumstances, the Academy may transfer a summary of its actions to a law enforcement agency, physician licensing authority, medical quality review board, professional peer review committee, or similar entity.

In addition to the issuance of the above mentioned advisory opinion, the Academy has sought to educate its members on the ethical and legal considerations surrounding various manufacturers offers. Articles appeared in the Academy's general newsletter, Argus, in

1983, 1984, and 1985, including an indepth review of the Health Care Financing Administration's guidelines to Medicare carriers on pacemaker and IOL rebates. The Academy cooperated with HCFA on the development of these guidelines. We have also maintained open communications with the HHS Inspector General's office on these and related issues. Indeed, in one Argus editorial, the Academy's counsel requested that "all Academy members furnish the Health Care Financing Administration . . . and other appropriate authorities with the names of all IOL manufacturers who offer remuneration in any form as an inducement to purchase those manufacturer's IOLs."

The Academy also plays a strong role in educating its members in the newest, most effective medical and surgical techniques, through a variety of regional "hands-on" courses, independent study, and lectures. These national continuing education courses have provided a foundation for the high quality care which ophthalmology offers to our senior citizens.

Along a different, but related track, the Academy publishes an annual supplement to our journal, a catalog of ophthalmic products. It is a "consumer's guide" designed to assist ophthalmologists in comparing the features and prices of equipment, devices, supplies and related ophthalmic products, including intraocular lenses. It is compliled by members of impeccable ethical standards, without advertising and without the influence of manufacturers or their sales forces. We believe that this guide may play a major part in assisting ophthalmologists to resist manufacturer's sales pressures.

In summary, the Academy condemns fraud, abuse and criminal activity, and applauds the efforts to prosecute those engaging in illegal and unethical practices. We will continue to offer our cooperation in maintaining high ethical standards for ophthalmology.

Reimbursement Issues Relating to Cataract Surgery

The Committee has identified anomalies in Medicare's payment methodologies relating to inpatient and outpatient cataract surgery. We will highlight some of the developments in recent years which have contributed to the variations in payment method and level. Prior to the enactment of the prospective payment system, hospitals "unbundled" certain Part A hospital costs into Part B. This occurred over a span of many years, at different rates, for different products and services, in different areas of the country. Hence, some hospitals billed intraocular lenses as surgical supplies under Part A; some as prosthetic devices under Part B. Physicians also began to supply the IOLS and bill Part B directly, either as a supplier of a prosthetic device, or as a service "incident to" the physician's services.

A major thrust of TEFRA, then of the prospective payment system was the "rebundling" of hospital inpatient services back into Part A. IOLs provided during inpatient cataract surgery were "bundled" into the fixed DRG rate for inpatient cataract surgery (DRG 39). At the same time, however, hospitals and physicians continued to bill for those IOLs provided during outpatient surgery under the various Part B payment methods.

Under the prospective payment system, hospitals receive a fixed price per case, based on DRG weights which were calculated from 1981 cost data. Unfortunately, the 1981 base data does not adequately reflect current utilization of IOLs during cataract surgery. We estimated that only 20 percent of the cataract patients received IOLs in 1981, whereas more than 80 percent received IOLs in 1984. As a result, DRG 39 underpays each inpatient cataract case with an IOL by $300-$400.

It appears that the combination of the fixed price for inpatient cataract surgery with IOL, the lack of price controls on hospital outpatient surgery, and the ambitious goals of the new Peer Review Organizations to decrease inpatient surgery have resulted in a revolutionary shift to outpatient cataract surgery. Outpatient surgery is not a new phenomenon. The Academy recognized an evolutionary trend toward outpatient surgery years ago, and has cooperated with HCFA in developing guidelines for outpatient surgery.

However, the Academy opposes the assumption by many government policy makers that if cataract surgery may be performed in an outpatient setting it must be performed outpatient. We urge that the physician must retain the option to perform cataract surgery on an inpatient basis according to his judgment of the patient's needs.

The Academy has taken an active role in the implementation of the prospective payment system. We filed comments with HCFA on the low weight attributed to DRG 39, cataract surgery, as previously discussed.

We have cooperated with the Prospective Payment Assessment Commission in its study of DRG 39 and the IOL cost issue. PROPAC's findings verified our estimates of the increased resource consumption under DRG 39 when a patient receives an IOL, which is not accounted for under the current weight. The new proposed rules, published by HHS on June 10, 1985 are based on 1984 cost data which reflect an increase of 16.4% for DRG 39.

In the area of Peer Review Organizations, the Academy and state ophthalmological societies have been monitoring state PRO activities. The majority of PROs established ambitious goals for reducing inpatient cataract surgery. In order to provide guidance to PROs, the Academy is in the process of developing minimum standards for cataract surgery, which could be applied at the local level. We testified before the Senate Finance Committee on our initial findings on PRO screening activities.

In addition, we reviewed and commented on a HCFA draft cost survey of ambulatory surgery centers, last summer, although it has not yet been conducted. The purpose of the survey would have been to establish the actual costs of operating a free-standing ambulatory surgery center. Currently, Medicare certified ASCs receive four levels of payment for the "facility" component of care, depending on the classification of the procedure. The facility component includes overhead, operating room expenses, nursing services, supplies, and other items as specified by HCFA. The surgeon's fee, as well as the cost of the IOL are billed independently. The four levels of facility payment are significantly below the DRG rate for the same procedure performed on an inpatient basis. For example, an average hospital currently would receive $1,500 for an inpatient cataract surgery with or without an IOL under DRG 39. A Medicare certified ASC would receive only $500 for the facility component of an outpatient cataract surgery, plus the cost of the IOL. Outpatient surgery performed in a hospital operating room is not controlled by either the DRG rate or the ASC facility rate. As a result, a range of payment amounts for hospital outpatient surgery have been reported.

Medicare will pay for cataract surgery in a variety of settings, and reimburse for IOLs using different methodologies associated with the setting or provider. As a result, there are documented inconsistencies in billing and payment levels, as well as a great deal of confusion and concern. For example, under Part A for a, inpatient procedure, a hospital may be losing a portion of the cost of the IOL under the DRG 39 rate. In the outpatient department, the hospital may receive more than the invoice price of the lens. An ambulatory surgery center may receive an amount equal to, more or less than the invoice price of the lens, depending on how the Part B carrier calculates reimbursement. The same is true for the physician who may be reimbursed an average allowable amount under a prevailing charge screen-which may not cover the cost of the occasional use of more expensive lenses.

Academy Recommendations.

The Academy has recognized the anomalies of current Medicare billing and payment methodologies for intraocular lenses. In a 1983 letter to HCFA Administrator, Carolyne Davis, we recommended the establishment of a standardized payment methodology for IOLs, based on acquisition cost plus a modest handling charge. IOLs acquired for a reduced price by a physician or facility because of manufacturers' discount should be billed at the net acquired reduced price plus handling. [5] Such a standardized methodology that could be applied throughout the industry would prevent misunderstanding, facilitate monitoring, and minimize fraud.

The Academy also suggests that there should not be extraordinary incentives toward one site of surgery or another. The surgeon should have the option to select the surgical setting based on patient needs, with cost as an important but secondary concern. This will ensure quality of care.

And, we recommend that Congress instruct HHS to establish on-going systems which will adjust reimbursement levels to eliminate inequities when they appear in an attempt to avoid situations which can lead to fraud and abuse.

Thank you for this opportunity to express our views. Dr. Bettman and I will be pleased to answer any questions the Committee might have.

FOOTNOTES

1. Kahn, H.A., Leibowitz, H.M., Ganley, J.P., et. al: The Framingham Eye Study: I. Outline and Major Prevalence Findings. American Journal of Epidemiology 106:17-32, 1977, in Vision Research: A National Plan 1983-1987. Report of the Cataract Panel. U.S. Department of Health and Human Services, Naitonal Institutes of Health, 1983, p.l.

2. Note: This figure represents both Medicare-covered and private-pay cataract cases. Source: Stark, W.J.; Leske, M.C.; Worthen, D.M., and Murray, G.C. "Trends in Cataract Surgery and Intraocular Lenses in the United States." American Journal of Ophthalmology, 1983; 96:304-10.

3. Excerpts from: Code of Ethics of the American Academy of Ophthalmology: A. Principles of Ethics; and B. Rules of Ethics.

4. Excerpts from: American Academy of Ophthalmology, Code of Ethics, Advisory Opinion 84-2, "Rebates and Other Payments to Ophthalmologists Related to the Purchase of Intraocular Lenses," approved by the Ethics Committee, May, 1984; approved by the Board of Directors, June, 1984.

5. Letter to Carolyne Davis, Ph.D., Administrator, Health Care Financing Administration, re: "Guidelines for Medicare coverage of Prostheses for Aphakia," from Robert Reinecke, M.D., Secretary of Governmental Relations, American Academy of Ophthalmology, September 20, 1983.

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September 20, 1983

Carolyne Davis, Ph.D.
Administrator
Health Care Financing Administration
Room 314-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Guidelines for Medicare
Coverage Of Prostheses For
Aphakia

Dear Dr. Davis:

The American Academy of Ophthalmology's Governmental Relations Committee recommends that the comprehensive service fee[1] which covers patient evaluation, lens and contact lens materials, fitting and follow-up should continue as a standard practice of Medicare reimbursement of prosethetic contact lens services provided by physicians. In order to prevent over-utilization of prosethetic devices, i.e. intraocular lens (IOL), contact lens or "cataract" spectacle services, administrative guidelines for the coverage of the prosthetic lenses supplied should be established.

We believe that considerable savings to both the Medicare program and Medicare beneficiaries — in the magnitude of millions of dollars — will result from the introduction of such guidelines.

Ophthalmologists have responsibility for follow-up care of their cataract patients throughout the 12 week postoperative period.[2] The surgeon has an obligation to provide the final examination and prescription of lenses to the patient who is pseudophakic or who will wear an aphakic spectacle correction. In the case of the patient who will wear a contact lens, an additional, separately-billed fee should include a follow-up period of 90 days from the time of the provision of the lens to the patient.

The Health Care Financing Administration's Atlanta Regional Office (Region IV) has submitted a report summarizing a review of Medicare payments for prosthetic lenses (including implanted intraocular lenses) in the Miami area and the State of Georgia.[3] The report recommends new reimbursement guidelines separating the cost of materials from patient evaluation and fitting services.

Presently, a comprehensive service fee is billed to Medicare which includes fitting and evaluation of a prosthetic device, provision of the prosthesis, and short-term aftercare for prosthesis suitability. The Region IV report suggests that the comprehensive fee has allowed too high a "mark-up" for the prosthetic lenses. Also, the report describes instances where the number of lenses prescribed per patient seemed excessive. The Medicare program currently has no consistent policy specifying the number of lenses it will reimburse per patient with a given time period.

Under Medicare, intraocular lens implants may be supplied and billed through either the operating surgeon or the hospital. There are wide variations in charges and levels of payment for IOLs. In some instances, as the Region IV study reveals, physicians are not receiving payment for the full IOL cost, while hospitals may be receiving reimbursement at levels in excess of twice the invoice cost.

The Academy's Committee for Governmental Relations has studied this situation and is recommending that the Medicare program, as well as other public and private third party payors, establish the following guidelines for reimbursement of prosthetic lens services and materials. For the purposes of these recommendations, the patient who has an intraocular lens is considered pseudophakic.[4] Similarily, for the purpose of these recommendations, the patient appropriately fitted with an aphakic contact lens is no longer functionally aphakic. However, payment should continue to be allowable for additional materials and services which exceed these guidelines if sufficient documentation is provided demonstrating medical necessity or other overriding individual considerations of the patient.

I. The comprehensive contact lens fee, including evaluation, materials and fitting fee should be maintained.

II. Reimbursement for spectacle prothesis for aphakia generally should be limited to:

(a) One pair of temporary spectacles when indicated and one pair of aphakic spectacle lenses during the first year after cataract surgery. (Bifocals and/or separate near and distance).

(b) One pair of aphakic spectacle sunglasses when medically indicated as necessary the first year after surgery.

(c) One pair or one lens change per year after the first year following surgery (2nd year and beyond). The change would have to be greater than one-half diopter in power or ten degrees in cylinder axis, and certified as such by the prescriber.

III. Reimbursement for the contact lens prosthesis for aphakia generally should be limited to:

(a) Two contact lenses per aphakic eye during the first year following cataract surgery. There shall be only one comprehensive contact lens service fee with the first lens or pair of lenses. Additional lens or pair of lenses shall be replacements. A maximum of one refitting device charge per year with submission of prescription change as certified by the prescriber.

(b) One contact lens replacement per eye per year for subsequent years following cataract surgery.

(c) comprehensive services fees should not be reimbursed with each replacement provided.

(d) Replacement charges should reflect invoice cost plus the handling. This will cover overhead and personnel costs.

(e) When contact lenses are fitted, one pair of aphakic spectacle bifocals during the first postoperative year should be covered. Replacements of aphakic spectacles for patients with an aphakic contact lens shall be the patient's responsibility.

IV. Reimbursement for the intraocular lens prosthesis for aphakia generally should be standardized:

(a) The ophthalmic surgeon or the hospital may be reimbursed for an intraocular lens implant at acquisition plus handling cost.

(b) IOLs acquired for a reduced price by an ophthalmic surgeon or hospital because of manufacturers' discount, rebate or bonus shall be billed at the net acquired reduced price plus handling.

As I noted earlier these guidelines, if implemented, have the potential of saving HCFA many millions of dollars for the Medicare program. We are therefore hopeful this recommendation receives favorable consideration. Should it be necessary we are available for consultation.

Sincerely,

Robert D. Reinecke, M.D.

Encl.

FOOTNOTES

1 Note: the term "comprehensive service fee" is used to capture the inclusive services and material provided to patients receiving a contact lens. This term is used to prevent confusion with the "global fee" which traditionally describes physician charges for surgical cases with post-operative care.

2 AAO Policy of February 21, 1982 (attached).

3 Health Care Financing Administration Program Validation Report, "Prosthetic Lenses (Florida and Atlanta Georgia)," Region, November 24, 1982 (1-04-1064-16). See our letter to you of August 22, 1983 (attached).

4 Pseudophakic: The condition of replacing the crystalline lens of the eye with a false lens.

Appendix One (1)

CODE OF ETHICS OF THE AMERICAN ACADEMY OF OPHTHALMOLOGY, INC. ("ACADEMY")

PREAMBLE

A. Principles of Ethics

The Principles of Ethics form the first part of this Code of Ethics. They are aspirational and inspirational model standards of exemplary professional conduct for all Fellows or Members of the Academy in any class of membership. They serve as goals for which Academy Fellows and Members should constantly strive. The Principles of Ethics are not enforceable.

B. Rules of Ethics

The Rules of Ethics form the second part of this Code of Ethics. They are mandatory and directive specific standards of minimally-acceptable professional conduct for all Fellows or Members of the Academy in any class of membership. The Rules of Ethics are enforceable.

C. Administrative Procedures

The Administrative Procedures form the third part of this Code of Ethics. They provide for the structure and operation of the Ethics Committee; and they detail procedures followed by the Committee and by the Board of Directors of the Academy in handling inquiries or challenges raised under the Rules of Ethics. All ophthalmologists who are Fellows or Members of the Academy in any class of membership are required to comply with these Administrative Procedures; failure to cooperate with the Ethics Committee or the Board of Directors in a proceeding on a challenge may be considered by the Committee and by the Board of Directors according to the same procedures and with the same sanctions as failure to observe the Rules of Ethics.

The Code of Ethics of the American Academy of Ophthalmology applies solely to the Academy and to its Fellows and Members, and is enforceable solely by the Academy. The Academy does not suggest or imply that any other medical society, organization, or association should adopt, implement, or enforce codes or standards of ethics which are the same as or similar in any respect to the Academy's Code of Ethics.

A. PRINCIPLES OF ETHICS

1. Ethics in Ophthalmology. Ethics are moral values. An issue of ethics in ophthalmology is resolved by the determination that the best interest of the patient is served.

2. Providing Ophthalmological Services. Ophthalmological services must be provided with compassion, respect for human dignity, honesty and integrity.

3. Competence of the Ophthalmologist. An ophthalmologist must maintain competence by continued study. That competence must be supplemented with the talents of other professionals and with consultation when indicated.

4. Communication with the Patient. Open communication with the patient is essential. Patient confidences must be safeguarded within the constraints of the law.

5. Fees for Ophthalmological Services. Fees for ophthalmological services must not exploit patients or others who pay for the services.

6. Identification of the Deficient Ophthalmologist. Those ophthalmologists who are deficient in character, or who engage in fraud or deception, should be identified to appropriate authorities.

7. Ethical Rules. It is the duty of an ophthalmologist to place the patient's welfare and rights above all other considerations. To this end one must subscribe to ethical rules which are for the benefit of the patient.

B. RULES OF ETHICS

1. Competence. An ophthalmologist is a physician who is educated and trained to provide medical and surgical care of the eyes and related structures. An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is. An ophthalmologist must not misrepresent credentials, training, experience, ability or results.

2. Informed Consent. The performance of medical or surgical procedures shall be preceded by appropriate informed consent.

3. Clinical Experiments and Investigative Procedures. Use of clinical experiments or investigative procedures shall be approved by adequate review mechanisms. Clinical experiments and investigative procedures are those conducted to develop adequate information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenesis, in circumstances in which insufficient information exists. Appropriate informed consent for these procedures must recognize their special nature and ramifications.

4. Other Opinions. Additional opinion(s) shall be obtained if requested by the patient. Consultation(s) shall be obtained if required by the condition.

5. The Impaired Ophthalmologist. A physically, mentally or emotionally impaired ophthalmologist should withdraw from those aspects of practice affected by the impairment. If the ophthalmologist does not withdraw, it is the duty of other ophthalmologists who know of the impairment to take action to assure withdrawal of the impaired ophthalmologist.

6. Preoperative Assessment. Surgery shall be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs. The preoperative work-up must document the indications for surgery. Performance of unnecessary surgery is an extremely serious ethical violation.

7. Delegation of Services. Delegation is the use of auxiliary health care personnel to provide eye care services for which the ophthalmologist is responsible. An ophthalmologist must not delegate to an auxiliary those aspects of eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must

be qualified and adequately supervised. An ophthalmologist may make different arrangements for the delegation of eye care in special circumstances, such as emergencies, if the patient's welfare and rights are placed above all other considerations.

8. Postoperative Care. The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist. The operating ophthalmologist may make different arrangements for the provision of those aspects of postoperative eye care within the unique competence of the ophthalmologist in special circumstances, such as emergencies or when no ophthalmologist is available, if the patient's welfare and rights are placed above all other considerations. Fees should reflect postoperative eye care arrangements with advance disclosure to the patient.

9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service.

10. Procedures and Materials. Ophthalmologists should order only those laboratory procedures, optical devices or pharmacological agents that are in the best interest of the patient. Ordering unnecessary procedures or materials for pecuniary gain is unethical.

11. Commercial Relationships. An ophthalmologist's clinical judgement and practice must not be affected by economic interest in, commitment to, or benefit from professionally-related commercial enterprises.

12. Communications to Colleagues. Communications to colleagues on research including clinical investigation must be accurate and truthful. Appropriate disclosure of commercial interest is required.

13. Communications to the Public. Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics or other means. They must not omit material information without which the communications would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way; and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments of the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent.

C. ADMINISTRATIVE PROCEDURES

1. Ethics Committee

(a) **The Committee.** The Board of Directors appoints at least five (5), but not more than nine (9), ophthalmologists who are Voting Fellows or Members of the Academy to serve three (3) year, staggered terms as members of the Ethics Committee. The Board of Directors makes its appointments to the Committee from among respected ophthalmologists who will, to the extent practicable, assure that the Committee's composition is balanced as to relative age and experience and as to the emphasis of the appointees upon practice, education, research or other endeavors within ophthalmology. Members of the Ethics Committee may serve no more than two three-year terms. However, a member appointed as Chairman or Vice Chairman of the Committee may serve no more than three three-year terms. Members may resign from the Committee at any time. Membership on the Ethics Committee may be terminated by the Board of Directors at any time and for any reason. Vacancies on the Committee are filled by the Board of Directors. Committee members are reimbursed for expenses. The Ethics Committee is responsible for (i) developing and implementing an educational program regarding the Code of Ethics among ophthalmologists and ophthalmologists-in-training who are Fellows or Members of the Academy, (ii) investigating each inquiry regarding ethics and recommending whether the Board of Directors should issue an advisory opinion interpreting the Rules of Ethics in this Code, (iii) investigating each challenge regarding ethics and recommending whether the Board of Directors should make a determination that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code, and recommending an appropriate sanction, and (iv) assessing the Principles of Ethics, Rules of Ethics and Administrative Procedures in this Code periodically and recommending any amendments to the Board of Directors.

(b) **The Chairman of the Committee.** Upon nomination by the President-Elect of the Academy, the Board of Directors appoints one member of the Ethics Committee as the Committee's Chairman to serve, at the will of the Board of Directors, as the principal administrative officer responsible for management of the promulgation, interpretation and enforcement of this Code of Ethics. The Board of Directors appoints as the Chairman a distinguished ophthalmologist who possesses recognized integrity and broad experience. The Chairman of the Committee is responsible directly and exclusively to the Board of Directors; the Chairman is reimbursed for expenses and, upon the approval of the Board of Directors, may be paid for services; and the Chairman is provided, upon the approval of the Board of Directors, with staff, legal counsel and other resources necessary to fulfill the responsibilities of administering this Code. The Chairman presides at, and participates in, all meetings and hearings of the Ethics Committee, except at any hearing at which the Committee considers the possible failure of a Fellow or Member of the Academy to observe the Rules of Ethics in this Code. The Chairman is responsible for ensuring that these Administrative Procedures are followed. The Chairman maintains liaison with entities, both public and private, which are interested or involved in medical ethics, particularly as they relate to ophthalmology.

(c) **The Vice Chairman of the Committee.** Upon nomination by the President-Elect of the Academy, the Board of Directors appoints a member of the Committee as the Committee's Vice Chairman to serve, at the will of the Board of Directors, in the place of the Chairman when the Chairman is unable to serve.

(d) **Meetings of the Committee.** Meetings of the Ethics Committee are called upon at least seven (7) days' written notice to Committee members, which notice includes a copy of the agenda for the meeting. A quorum consists of a majority of all of the appointed Committee members. Voting is by majority of those present at a meeting (or by a majority of those submitting votes in a mail vote). Mail voting without a meeting is permitted where all Committee members submit mail votes or abstentions. Voting by proxy is not permitted. A member of the Committee must decline to participate in the consideration of, or the decision in, any matter before the Committee in which the member has a personal interest.

(e) **Indemnification and Insurance.** All Ethics Committee members, staff, and other individuals engaged in investigations at the written request of the Chairman, are indemnified and defended by the Academy against liability arising from Committee-related activities to the extent provided by the Bylaws of the Academy for Directors, Officers, employees and agents. The Academy maintains indemnification insurance against such liability.

2. Inquiries and Challenges

(a) **Preliminary Review.** The Chairman preliminarily reviews each submission involving this Code of Ethics to consider whether it may be an inquiry (*i.e.*, a request for issuance by the Board of Directors of an advisory opinion interpreting the Rules of Ethics in this Code) or a challenge (*i.e.*, a request for a finding by the Board of Directors that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code). A submission involving this Code of Ethics, whether or not it is designated or phrased as an inquiry or challenge, may be construed by the Chairman or the Committee as either an inquiry or a challenge in the light of information in the submission. Inquiries may be considered without regard to their means or form of submission. Challenges are not considered unless they are submitted in writing and signed by their submitters. Inquiries or challenges may be submitted by ophthalmologists (whether or not they are Fellows or Members of the Academy), other physicians, health care institutions, health care reimbursers, allied health professionals, patients or organizations representing any of these.

(b) **Preliminary Disposition.** Upon preliminary review of a submission involving this Code of Ethics, the Chairman may conclude, in the Chairman's sole discretion, that the submission (i) contains insufficient information on which to base an investigation or (ii) is patently frivolous or inconsequential, *i.e.*, it does not present an issue of interpretation of the Rules of Ethics in this Code adequate to constitute a valid and actionable inquiry and to justify bringing the submission before the Committee for investigation and recommendation to the Board of Directors on issuance of an advisory opinion or it does not present an issue of the failure of a Fellow or Member of the Academy to observe the Rules of Ethics in this Code adequate to constitute a valid and actionable challenge and to justify bringing the submission before the Committee for investigation and recommendation to the Board of Directors on a determination of failure to observe the Rules of Ethics. If so, the submission is disposed of by notice from the Chairman to its submitter, if the submitter is identified. Each such preliminary disposition by the Chairman of a submission involving this Code of Ethics is reported to the Ethics Committee.

(c) **Investigation.** For each submission involving this Code of Ethics that the Chairman concludes is a valid and actionable inquiry or challenge, the Committee conducts an investigation into its specific facts or circumstances to whatever extent is necessary in order to clarify, expand or corroborate the information provided by the submitter or in order to determine, with respect to a challenge, whether it is most appropriately raised under the Rules of Ethics in this Code and considered further by the Ethics Committee and Board of Directors rather than by some other entity engaged in the administration of law or the regulation of the conduct of physicians, such as a law enforcement agency, physician licensing authority, medical quality review board or professional peer review committee. The Chairman supervises each investigation and may conduct an investigation personally. The Chairman may be assisted in the conducting of an investigation by other Ethics Committee members or by Committee staff. The Chairman may also be assisted by any other individual such as a member of the Board of Councilors of the Academy (i) whose location, professional position or expertise might facilitate the investigation, (ii) whose assistance is requested in writing by the Committee Chairman, and (iii) who agrees in writing to follow the Administrative Procedures of this Code; but only when all three (3) of those conditions are fulfilled. A Fellow or Member of the Academy who is the subject of a valid and actionable challenge is informed in writing at the beginning of the Committee's investigation as to (i) the nature of the challenge, (ii) the obligation to cooperate fully in the Committee's investigation of the challenge, and (iii) the opportunity to request a hearing on the challenge before the Ethics Committee. Investigations involving challenges are conducted in confidence, with all written communications sealed and marked "Personal and Confidential," and they are conducted objectively, without any indication of prejudgement. An investigation may be directed toward any aspect of an inquiry or challenge which is relevant or potentially relevant.

3. Proceeding on Inquiries

(a) **Hearing on an Inquiry.** In the course of an investigation involving an inquiry, the Committee may conduct a public administrative hearing to receive the views of those who are interested in, or may be affected by, issuance by the Board of Directors of an advisory opinion interpreting the Rules of Ethics in this Code. Thirty (30) days' written notice of the hearing is given to the Fellows and Members of the Academy and to others who, in the opinion of the Committee, may be interested in, or affected by, issuance of advisory opinion. The notice may include a tentative proposed advisory opinion. The hearing is conducted by the Committee with any three (3) or more Committee members participating. The Chairman of the Committee serves as the Hearing Officer to preside at the hearing and assure that these Administrative Procedures are followed. The Hearing Officer may issue any appropriate procedural or evidentiary ruling in the course of the hearing and may be assisted by legal counsel. The Hearing Officer presents at the hearing the issues raised by the inquiry, the results of the investigation up to the time of the hearing, and any tentative proposed Committee recommendation to the Board of Directors for an advisory opinion. Information is offered through witnesses, who may be assisted by legal counsel and are subject to questioning by the Committee. Any information may be considered which is relevant or potentially relevant. A transcript or recording of the hearing is made. The official record of the hearing becomes part of the investigation of the inquiry.

(b) **Recommendation on an Inquiry.** Upon completion of an investigation involving an inquiry, the Ethics Committee recommends whether the Board of Directors should issue an advisory opinion interpreting the Rules of Ethics in this Code. If the Committee so recommends, a proposed advisory opinion is prepared under the supervision of the Chairman and is submitted to the Board of Directors along with a summary of the record of the Committee's investigation. The Board of Directors has access to the entire record of the investigation. If the Committee recommends against issuance of an advisory opinion, the inquiry is dismissed with notice to its submitter, if the submitter is identified, and a summary report is made to the Board of Directors.

(c) **Advisory Opinion.** The Board of Directors issues an advisory opinion interpreting the Rules of Ethics in this Code (i) upon the recommendation of the Ethics Committee arising from an inquiry and following an investigation or (ii) upon the recommendation of the Committee arising from its own initiative. A representative of the Committee presents to the Board of Directors, for its review, the recommendations of the Committee and its record of the investigation. Once issued by the Board of Directors, the advisory opinion is promulgated by publication to the Fellows and Members of the Academy. Advisory opinions are compiled by the Ethics Committee; and the compilation is periodically made available to the Fellows and Members of the Academy.

4. Proceedings on Challenges

(a) **Hearing on a Challenge.** In the course of an investigation involving a challenge, the Committee conducts a private adjudicative hearing if one is requested by the Fellow or Member of the Academy who is the subject of the challenge or at the

Committee's own initiative. Thirty (30) days' written notice of the hearing is given to the Fellow or Member. The hearing is conducted by the Committee with any three (3) or more Committee members participating, other than (i) the Chairman, (ii) any Committee member who assisted substantially in the investigation of the challenge, and (iii) any Committee member whose professional activities are conducted at a location in the approximate area of that of the Fellow or Member of the Academy who is the subject of the challenge. Those Committee members participating in the hearing elect from their number of Hearing Officer to preside at the hearing and assure that these Administrative Procedures are followed. The Hearing Officer may issue any appropriate procedural or evidentiary ruling in the course of the hearing and may be assisted by legal counsel. The Chairman of the Committee presents to the Committee at the hearing the results of the investigation up to the time of the hearing. The Fellow or Member of the Academy who is the subject of the challenge, who may be assisted by legal counsel, may refute the results of the investigation and may offer any exculpatory information. The Chairman and the Fellow or Member may offer information through witnesses, who are subject to cross-examination and questioning by the Committee. Any information may be considered which is relevant or potentially relevant. A transcript or record of the hearing is made. The hearing is closed to all except the Committee, the Chairman, the Fellow or Member of the Academy who is the subject of the challenge, their witnesses and counsel, staff and official reporter. The official record of the hearing becomes a part of the record of the investigation of the challenge.

(b) **Recommendation on a Challenge.** Upon completion of an investigation involving a challenge, the Ethics Committee recommends whether the Board of Directors should make a determination that the Fellow or Member of the Academy who is the subject of the challenge has failed to observe the Rules of Ethics in this Code. When the Committee recommends a determination by the Board of Directors of non-observance, the Committee also recommends imposition by the Board of Directors of an appropriate sanction. If the Committee so recommends, a proposed determination with a proposed sanction is prepared under the supervision of the Chairman and is presented by a representative of the Committee to the Board of Directors along with the record of the Committee's investigation. If the Committee recommends against a determination of non-observance, the challenge is dismissed, with notice to the Fellow or Member of the Academy who is the subject of the challenge and to the submitter of the challenge, and a summary report is made to the Board of Directors.

(c) **Determination of Non-Observance.** The Board of Directors makes the determination whether a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code and imposes an appropriate sanction upon the recommendation of the Ethics Committee arising from a challenge and following an investigation. The Board of Directors reviews the recommendation of the Committee based upon the record of the investigation. The Board of Directors may accept, reject or modify the Committee's recommendation, either with respect to the determination of non-observance or with respect to the sanction. If the Board of Directors makes a determination of non-observance, this determination and the imposition of a sanction are promulgated by written notice to the affected Fellow or Member of the Academy and to the submitter of the challenge, if the submitter agrees in advance and in writing to maintain in confidence whatever portion of the information is not made public by the Board. Additional publication occurs only to the extent provided in the sanctions themselves. If the Board of Directors does not make a determination of non-observance, the challenge is dismissed, with notice to the affected Fellow or Member and to the submitter of the challenge.

(d) **Alternative Disposition.** Before the Committee makes any recommendation to the Board of Directors as to a determination that a Fellow or Member of the Academy has failed to observe the Rules of Ethics in this Code, the Committee may request that the Board of Directors offer the Fellow or Member an opportunity to submit a written assurance that the possible non-observance has been terminated and will not recur. The decision of the Ethics Committee on whether to request that the Board of Directors extend such an offer is entirely within the Committee's own discretion, based upon its investigation of the challenge and upon its assessment of the nature and severity of the possible non-observance when viewed from the point of view of what is in the best interests of patients of the Fellow or Member of the Academy who is the subject of the challenge. The decision of the Board of Directors whether to subsequently extend such an offer is likewise entirely within the Board's own discretion. If an offer is extended, the Fellow or Member of the Academy must submit the required written assurance within thirty (30) days of receipt of the offer; and the assurance must be submitted in terms that are acceptable to the Board of Directors. If the Board of Directors accepts the assurance, notice is given to the submitter of the challenge, if the submitter agrees in advance and in writing to maintain the information in confidence.

(e) **Sanctions.** Any of the following sanctions may be imposed by the Board of Directors upon a Fellow or Member of the Academy who, the Board has determined, has failed to observe the Rules of Ethics in this Code, although the sanction applied must reasonably relate to the nature and severity of the non-observance, focusing upon reformation of the conduct of the Fellow or Member and deterrence of similar conduct by others:

(i) Reprimand to the Fellow or Member of the Academy, with publication of the determination but not the Fellow's or Member's name;

(ii) Suspension of the Fellow or Member from the Academy for a designated period, with publication of the determination and with or without publication (at the discretion of the Board of Directors) of the Fellow's or Member's name; or

(iii) Termination of the Fellow or Member from the Academy, with publication of the determination and of the Fellow's or Member's name.

Fellows or Members of the Academy who are suspended are deprived of all benefits and incidents of membership during the period of suspension, except continued participation in Academy insurance programs. In addition, if the Fellow or Member is suspended with publication of the name or terminated, and, if an appeal is submitted and it ultimately sustains the determination on which the sanction is based, the Board of Directors may authorize the Ethics Committee to communicate the determination and transfer a summary or the entire record of the proceeding on the challenge to, and at the request of, an entity engaged in the administration of law or the regulation of the conduct of physicians, in a proceeding that relates to the subject matter of the challenge, provided, however, that that entity is a law enforcement agency, physician licensing authority, medical quality review board, professional peer review committee, or similar entity; and the Chairman of the Ethics Committee may appear if requested as a witness to that determination and record. Except in the instance of communication of the determination and transferral of the record, or in the instance of request of the record by the Fellow or Member of the Academy who was the subject of the challenge, the entire record, including the record of any appeal, is sealed by the Ethics Committee and the Board of Directors and no part of it is communicated by the members of the Board of Directors, the members of any appellate body, the members of the Ethics Committee, the staff or any others who assisted in the proceeding on the challenge, to any third parties. Fellows or Members of the Academy who are terminated may not reapply for membership in any class.

(f) **Appeal.** Within thirty (30) days of receipt of notice of a determination by the Board of Directors that a Fellow or

Member of the Academy has failed to observe the Rules of Ethics in this Code and of imposition of a sanction, the affected Fellow or Member may submit to the Board in writing a request for an appeal. The Board of Directors establishes an appellate body consisting of at least three (3), but not more than five (5), ophthalmologists who are Voting Fellows or Members of the Academy and who did not participate in the Ethics Committee's investigation or in the Board of Director's determination. The appellate body conducts and completes the appeal within ninety (90) days after receipt of the request for an appeal. The purpose of the appeal is to provide an objective review of the original challenge, the investigation and recommendation of the Ethics Committee, and the determination of the Board of Directors, but not, however, the sanction imposed. The appeal is limited to a review of the Ethics Committee's and Board of Directors' application of the Rules of Ethics in this Code to the facts established in the investigation of the challenge and to a review of the procedures followed to ascertain whether they were consistent with those detailed in these Administrative Procedures. An appeal may not take into consideration any matters not included as part of the record of the Ethics Committee's investigation and the Board of Directors' determination. The appeal consists of a review by the appellate body of the entire record of the proceeding on the challenge and written appellate submissions of the Fellow or Member of the Academy who was the subject of the challenge and of the Board of Directors. Written appellate submissions and any reply submissions may be made by authorized representatives of the Fellow or Member and of the Board of Directors. Submissions are made according to whatever schedule is established by the appellate body. The decision of the appellate body either affirms or overrules the determination of the Board of Directors on non-observance of the Rules of Ethics in this Code by a Fellow or Member of the Academy. The decision does not address the sanction imposed by the Board of Directors. The decision of the appellate body, including a statement of the reasons for the decision, is reported to the Board of Directors. The decision is binding upon the Board of Directors, the Fellow or Member who is subject of the challenge, the Ethics Committee and all other persons.

(g) **Resignation.** If a Fellow or Member of the Academy who is the subject of a challenge resigns from the Academy at any time during the pendency of the proceeding of the challenge, the challenge is dismissed without any further action by the Ethics Committee, the Board of Directors or an appellate body established after an appeal; the entire record is sealed; and the Fellow or Member may not reapply for membership in any class. However, the Board of Directors may authorize the Ethics Committee to communicate the fact and date of resignation, and the fact and general nature of the challenge on which a proceeding was pending at the time of the resignation, to, and at the request of, an entity engaged in the administration of law or the regulation of the conduct of physicians, in a proceeding that relates to the subject matter of the challenge, provided, however, that that entity is a law enforcement agency, physician licensing authority, medical quality review board, professional peer review committee, or similar entity.

Advisory Opinions on the Code of Ethics of the American Academy of Ophthalmology

SUBJECT: *Rebates and Other Payments To Ophthalmologists Related to the Purchase of Intraocular Lenses* 84-2

ISSUES RAISED: To what extent is it ethical for an ophthalmologist to accept rebates, payments, or other things of value from vendors of intraocular lenses in connection with his/her prescribing their products.

APPLICABLE RULES: "Rule 11. Commercial Relationships. An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises."

"Rule 10. Procedures and Materials. Ophthalmologists should order only those laboratory procedures, optical devices or pharmacologic agents that are in the best interest of the patient. Ordering unnecessary procedures or materials for pecuniary gain is unethical."

"Rule 9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service."

"Principle 5. Fees for Ophthalmological Services. Fees for ophthalmological services must not exploit patients or others who pay for the services."

OTHER REFERENCES: *See also* (1) Current Opinions of the Judicial Council of the American Medical Association, §6.03 ("Fee Splitting"), §6.05 ("Fee Splitting: Drug Prescription Rebates"), and §8.06 ("Drugs and Devices: Prescribing"); (2) 42 United States Code §§1395nn, 1396h.

CIRCUMSTANCES OF THE INQUIRY

Dr. Wilson is an ophthalmologist with an active practice in cataract/intraocular implant surgery. He has used many different types of IOLs provided by a number of suppliers. After observing results in his patients, increasingly he has come to favor a particular IOL, the J-Loop manufactured by *Apex Co.* He has implanted about 800 Apex J-Loops per year for the past few years. Last year, Dr. Wilson was approached by a sales representative of Apex who told him that Apex had instituted an Incentive Plan under which ophthalmologists who purchase Apex J-Loops in excess of a certain volume would receive shares of stock in Apex (currently selling at $10/share) according to the following schedule:

IOLs Purchased in a Year	Shares Earned
200–400	5 shares
400–800	15 shares
800–1600	60 shares
1600–2400	200 shares
2400–3200	500 shares

Dr. Wilson decided to participate in the plan. During the first year, Dr. Wilson ordered 700 Apex J-Loops and received 15 shares of stock.

Dr. Wilson has become a very well-known and widely respected ophthalmic surgeon. In recent months, he has been approached by a number of other IOL manufacturers who have proposed various incentives to get him to use their products. They include the following:

Best Co. has proposed a "Volume Discount Plan" under which Dr. Wilson would pay $450 per lens for the first 200 lenses he orders, $425 per lens for the next 400 lenses, $375 per lens for the next 400 lenses, and $300 per lens for all lenses thereafter.

Care Co. has proposed a "Volume Discount Plan" under which they provide a 10% discount on all IOL orders of 200 or more at one time, and an added 5%

discount on orders at one time in excess of 500, if payment is made within 30 days.

Darby Co. has instituted an Incentive Plan under which an ophthalmologist who purchases more than 500 lenses in a year receives one free lens for every 10 lenses he/she purchases in excess of 500.

Ester Co. has a "Customer Rebate" plan under which any ophthalmologist who orders more than 100 of its IOLs receives a $10 rebate in cash for every IOL purchased thereafter.

Fine Co. has a "Customer Appreciation Plan" under which they invite all ophthalmologists who purchase more than 2000 of their lenses in any year to be guests of Fine Co. for an all-expenses-paid week-long meeting of the "2000 Club" in the Bahamas, at which scientific papers and promotional messages concerning the success of Fine Co.'s IOLs are presented.

Dr. Wilson is a Fellow of the Academy and wishes to know whether it is ethical for him to continue participating in the Apex Incentive Plan and whether he could ethically participate in any of the other plans. The representative of each company has advised him that he may lawfully keep the benefits under the plan and charge his usual fees.

RESOLUTION OF THE ISSUES RAISED

In most circumstances, it would probably be unethical for Dr. Wilson to participate in any of these plans except that of Care Co.—unless he directly passed on to his patients and/or third-party payors the true value of the benefits he receives.

The fundamental principles of the Code of Ethics in this area are those set forth in Rule 11, that "an ophthalmologist's clinical judgment and practice must not be affected by economic interest[s]" and in Rule 10, that an ophthalmologist should order "only those . . . optical devices . . . that are in the best interest of the patient." The ophthalmologist's subjective belief that his/her clinical judgment to use a particular lens is unaffected by the attractive incentive plan provided by the manufacturer, is not itself sufficient. If subjective belief in one's own motives were sufficient, objective ethical rules for professional conduct could rarely be enforced. The psychological reality is that a person cannot always sort out all his/her motives. Medical device manufacturers skillfully combine appeals based on scientific information, personal contact, professional relations, and economic incentives. Therefore, an ophthalmologist should guard against unwittingly having his/her clinical judgment colored—by scrupulously avoiding economic arrangements which might affect such judgment. Whenever an ophthalmologist receives any thing of substantial value from a device vendor, simply for ordering its products, there is potential for distortion of his/her clinical judgment, distortion of the doctor/patient relationship, and an ethical conflict.

In addition, although the Code of Ethics does not explicitly proscribe arrangements which may create the *appearance* of impropriety, the better course is certainly to avoid economic arrangements which reasonably may lead patients to believe that the ophthalmologist has his/her own economic interests in mind rather than the patients' best interests. In the case of Dr. Wilson, it also is not a defense that the aggregate number of Apex J-Loops has not increased. There is still the potential for his clinical judgment being affected, such as in resisting switching to new or better devices.

While Advisory Opinions such as this resolve questions only under the Academy's Code of Ethics, it is important to note that other legal and ethical rules to which ophthalmologists' conduct may be subject may impose even more stringent rules. For example, the Medicare and Medicaid laws (42 U.S.C. §§ 1395nn, 1396h) make it a criminal act, in connection with the provision of any medical care for which Medicare/Medicaid payment is sought for an individual to solicit or receive "any remuneration (including any . . . rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing, . . . ordering, or arranging for or recommending purchasing, . . . or ordering any good, facility, service, or item." The only relevant exception is a "discount or other reduction in price obtained by a provider of services or other entity . . . if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity."* Under these laws, a number of legal decisions have upheld criminal convictions of health professionals or others for receiving payments in exchange for arranging particular ancillary services for patients.†

This is a complicated area in which certain aspects of the law are unclear. This Advisory Opinion does not seek to define the limits of the law. Ophthalmologists should consult with their own legal counsel concerning transactions which may possibly be of this kind. What is clear for ethical purposes under the Code of Ethics is that conduct which is even close to that which may be illegal surely raises serious ethical issues.

In addition, ophthalmologists should be aware of very stringent rules of the Judicial Council of the American Medical Association in this area. Section 6.03 of the Opinions of the Judicial Council states unequivocally that "*A physician may not accept payment of any kind, in any form, from any source, such as . . . an optical company* or the manufacturer of medical devices and appliances for prescribing or referring a patient to said source." (Emphasis supplied.)

We believe that most difficulties in this area can be avoided by observing several basic tenets: (1) the ophthalmologist should either decline any payment or other thing of value (including a discount) offered by an intraocular lens vendor, or (2) if appropriate, accept it, pass along to the patient (and/or third party payors) the true value of the benefit, and disclose to the patient (or third-party payors) that the true costs will be reflected in the ophthalmologist's charges. It should be noted that because of certain overhead costs (storage, insurance, inventorying), the ophthalmologist may not in fact receive, and may not need to pass on, all discounts or similar payments on a dollar-for-dollar basis. However, he/she must pass on the *true benefit* (s)he receives. If an ophthalmologist passes on to the patient and/or third-party payors the true value of any rebate or reduction in price, then there can be no claim that his/her "clinical judgment and practice has been affected." (Rule 11.) These steps should also insure that the ophthalmologist orders only those devices "that are in the best interest of the patient," (Rule 10), and that (s)he does not "misrepresent the service that is performed or the charges made for that service." (Rule 9.)

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* The procedures necessary to insure disclosure and proper crediting of reductions in price under the transition to full DRG-based prospective payment are complex, and beyond the scope of this Advisory Opinion. However, the principle of disclosure and pass-through of the true benefit or discount are clear.

† See, e.g., *United States v. Hancock*, 604 F.2d 999 (7th Cir. 1979) (payments in exchange for referring blood and tissue samples to clinical laboratory held to be kickback); *United States v. Universal Trade and Industries*, 695 F.2d 1151 (5th Cir. 1983) (same); *United States v. Duz-Mor Diagnostic Laboratory, Inc.*, 650 F.2d 223 (9th Cir. 1981) (payment to nursing home operators for using clinical lab); *United States v. Perlstein*, 632 F.2d 661 (6th Cir. 1980) (gifts of cash and liquor to nursing home operator); *United States v. Ruttenberg*, 625 F.2d 173 (7th Cir. 1980) (fees paid by pharmacist for the right to serve nursing home patients); *United States v. Tapert*, 625 F.2d 111 (6th Cir. 1980) (payments to physicians for lab referrals).

Analyzing why ophthalmic device manufacturers offer discounts and rebates demonstrates the inappropriateness of most such arrangements. One has only to ask this question: Why is the device manufacturer offering an incentive plan or "volume discount" rather than simply reducing the price on every unit, beginning with the first, and thereby competing based on price? If a firm offers a 5% discount on all purchases of its products *from the first unit on*, it is simply engaging in price competition. Why does it do otherwise? There can only be two answers. The first is that some volume discounts reflect the true *transactional cost-efficiencies* of bulk sales (eg, less paperwork, less shipping costs, prompt payment). For example, it is usually more efficient for a producer to sell 1000 bottles of catsup to a restaurant rather than one bottle to each of 1000 consumers. If a discount is related to such cost-savings to the seller, it is not in any way objectionable. But if it clearly exceeds that amount, then it must be intended to achieve the second purpose of a volume discount. Its purpose is to persuade the purchaser-ophthalmologist to use more of the seller's lenses, ie, to purchase such lenses for *cases in which he/she would not otherwise deem them the lens of choice*. Thus, the ophthalmologist has been affected in his/her clinical judgment to the detriment of the patient.

Moreover, the way in which many of these incentive schemes are scaled is suggestive: no benefit accrues until one purchases a threshold amount, and then the marginal economic benefit increases with ever larger purchases, putting increasing pressure on ophthalmologists to use a particular lens for *all* patients regardless of appropriateness. For these reasons, such inducements are generally inappropriate.

If the true benefits are passed on to the patient, however, the incentive to the ophthalmologist is eliminated, and the patient essentially receives the economic benefits of competition. In a sense, the ophthalmologist still benefits professionally, however. If he/she is an efficient, high-volume user and can therefore earn a greater discount, he/she may be able to offer the patient a larger price pass-through.

Thus, in the absence of disclosure and pass-through of the benefits, all the proposed plans are unethical. The *Apex Co.* plan is patently unethical. Not only would it be impossible to pass on to the cataract patient (pro rata) the fluctuating value of the stock received, but by virtue of receiving *stock* in Apex Co. on a continuing basis, Dr. Wilson could easily be seduced into a continuing loyalty to Apex. No doubt this is why Apex thought rebates in the form of stock would be a clever marketing technique.

The *Best Co.* plan is also objectionable (unless the savings are disclosed and passed on). We note particularly the rapid escalation of "discounts" (from roughly 6% after 200 lenses to 33% after 1000 lenses), which suggests both a cross-subsidy among patients of different ophthalmic prescribers, and the tremendous margin on which the company must operate if it can provide large bonuses for referral of patients, while still making a profit on the price of each lens.

The *Care Co.* arrangement is the least objectionable and might in fact be acceptable in light of other circumstances. The volume discount is available to anyone who orders in bulk at a relatively low level, and seems reasonably related to transaction efficiencies.

The *Darby Co.* plan is not materially different from that of Best Co.; it makes no difference ethically whether Dr. Wilson receives a rebate in cash, or in the form of lenses for which he can then charge patients or other payors.

The *Ester Co.* plan is a pure "kickback," not a volume discount.

The *Fine Co.* plan is simply a bribe or kickback paid to an ophthalmologist. Window-dressing "seminars" do not transform a free vacation in the Bahamas into a scientific conference which is paid for by the ophthalmologist.

We also wish to make clear that myriad kinds of arrangements exist in the marketplace. The examples given above are skeletal ones only; additional factors might mitigate or exacerbate the ethical problems of such plans. However, some flexibility certainly is warranted, so long as the purpose and effect of a plan is to help patients, rather than simply to benefit ophthalmologists.

Finally, it must be stressed that this Advisory Opinion addresses only the subject of payments to ophthalmologists in exchange for their prescribing intraocular lenses. This opinion does not address other issues, such as payments by optical companies to ophthalmologists for research, clinical investigation, medical consultation, or promotional efforts—which may involve other serious ethical issues. Nor does this opinion address the issue of discounts on frames, spectacles or other products. While some analogous principles may apply, and ophthalmologists should consider carefully the ethical implications of such arrangements, we do not resolve such matters in this Advisory Opinion.

APPROVED BY THE ETHICS COMMITTEE IN MAY, 1984
APPROVED BY THE BOARD OF DIRECTORS IN JUNE, 1984

Mr. **Pepper**. We are particularly pleased to have you here representing your academy.

You have said most of—what percent of all the ophthalmologists?

Dr. **Aquavella**. Approximately 90 percent.

Mr. **Pepper**. They are represented by your association. I am a lawyer, and the Bar Association, and an association ought to discipline its own members. In the same way your association ought to lay down the standards for observance by your members, and we are particularly pleased to have you and Dr. Bettman here who is chairman of the ethics committee of your academy.

I will have some more questions for you in a minute.

Dr. Jerome Bettman, chairman of the ethics committee of the Ophthalmologist Association.

STATEMENT OF JEROME BETTMAN, M.D.

Dr. **Bettman**. I, too, am an ophthalmologist, emeritus clinic professor at both Stanford University and the University of California as well as chairman of the ethics committee of the American Academy of Ophthalmology.

I have been interested in the problems of older people, and as a matter of fact, am on the founding editorial board of geriatric ophthalmology.

I want to make it crystal clear that the simple American principles of integrity and honesty are not dead.

Now, as you have heard, we are dealing with 13,500 ophthalmologists. Of course, in any group of that size there are going to be some people that take advantage, some so-called bad apples, but believe me, we are dealing with them. We designed this code of ethics that we have with just one thing in mind, and continually when our committee discusses it, we ask the question, "is it for the good of the patients."

That is the only thing in that code of ethics, that, I think, perhaps you have it in your addendum, and if you do have the time to look at it, you will see that every word in there is designed for the good of the patient and nothing else.

Now, we are totally in favor of and applaud your efforts, and the Senator's efforts, to do something about the cheaters and the people that take advantage. We have no control over manufacturers, because we are just a committee of ophthalmologists, but believe me, we are proceeding against those people who are out of line, and I will tell you, that it is and will be our number one priority.

Now, it has been said that medicine should clean its own house. We are in the process of cleaning it and I have the handle of the broom, and I will assure you, or as perhaps Shakespeare once said, I shall guarantee—note the use of the positive "shall"—that this will be our number one priority.

We are meeting in Boston in a little over a week. We are really working on it. We have been working on it before but we are going to exert more effort.

We are totally opposed to kickbacks in any form, except with one little variation, and that is, that if an ophthalmologist is given a reduction of, say, $75 or $100 on intraocular lens implant, and he says to his patient or to third party payor, I am getting this for $75 or $100 less, so you are going to be charged that much less, that is acceptable.

With that exception, nothing is acceptable, be it in direct payment or a trip to Bermuda or whatever, nor these various instruments that were talked about. Unnecessary surgery is considered a most serious violation of our code of ethics, and those very words are in the code of ethics.

Let me perhaps say a few things to balance some of the statements that have been made up until now.

What is the reason that we have shifted from this long hospitalization of 3 to possibly 7 days or more for cataract extracts? One is that there has been a vast improvement in technique. We now have suture material, needles and so on, that are much more adequate. We can close the wound tightly.

We can let a person go early whereas we couldn't before but there are exceptions, and there are certain people who will require not just ambulatory care in a center but hospital care, and I think it would be an egregious error if anyone were to limit all of these things to outpatient surgery or ambulatory care.

It must be left to the judgment of the physician. Why? Because unlike mechanical things, robots and so on, we can't turn a screw a certain number of times and always get the same effect. There are so many variations and in the biological organism we must rely on the physician's judgment, the surgeon's judgment.

That is the reason physicians have to go through such an enormously long period of training. It is for judgment. I could train a young fellow to do some types of surgery in a relatively short time, but it takes years to train people to have good judgment and it is this very judgment that we must depend upon the physician for and not have it firmly legislated.

The same thing is true of assistant surgeons. There are times when assistant surgeons are not necessary, but there are times when they are vital. For example, if you have to make a larger incision than usual, with sutures in the cornea, or perhaps a light pipe is put into the very interior of the eye so the surgeon can look back at the retina if there are complications of the cataract, and at the same time, he must also put in an instrument through another portal which is capable of sucking out some of the vitreous fluid which may be necessary when some complications occur, and at the same time put in microscopic instruments that he can see with and these things would not be done without an assistant surgeon. It is necessary to have four or even six hands at times.

Here again I would urge you not to make absolute rules, because I must go back to the fact that it must depend upon the surgeon's judgment.

One other thing that perhaps one should consider, put in the hopper, let us say, in regard to costs.

I am most in favor of reducing costs where we can, and I am appalled when people take advantage of Medicare, but as I say, there are other things that must be considered, including the cost of malpractice insurance.

A while back I was chairman of the medical/legal committee for the University of California. We had to pay $17 million a year for our malpractice coverage.

Individuals don't pay anything like that figure, but nevertheless, the rates are really high, and I am sure the figures are available to you. I don't have really reliable statistics in front of me, but I think these various things should be put in the hopper and I will leave you with just a few thoughts.

A, we in ophthalmology are cleaning our house. Believe me. We are going to expel some of these rascals and publish their names, and those names can get back to all the other authoritative government agencies and what not.

In addition to that, though, one must keep in mind, we are not dealing with robots. We must leave things up to a physician's judgment, and I think insofar as costs are concerned, one should look at the entire picture.

Thank you. I am delighted to be here and I want to compliment you and your committee and the Senator, too, in doing his work in what we well know is necessary.

Mr. PEPPER. Dr. Bettman, I think Shakespeare in another place said, "Out, out, damn spot."

Put your quote and mine together, we can get something done then. We are particulary pleased to have Dr. Aquavella and you, Dr. Bettman, because you have the primary responsibility of disciplining your membership and holding up the standards that your organization wishes to portray and to observe.

There is one thing that complicates the situation a great deal, and that is that there is a double system of charging under Medicare.

I think it is apparent that in some instances—by the way, before I say that, how is the bill submitted by the one who sells the IOL?

Mr. AQUAVELLA. The invoice?

Mr. PEPPER. Do they submit one bill for that little instrument?

Mr. AQUAVELLA. Sometimes they do and sometimes they don't.

Usually what happens is that an ambulatory surgical center or a hospital unit maintains a certain amount of inventory of these lenses because they all come in different powers and sizes, like shoes, if you will, and then, of course, there are surgeon preferences that have absolutely nothing to do with incentives, abuse, or fraud.

Some surgeons feel an anterior placement is better. Another surgeon might feel a posterior placement is better. Another surgeon might think this design is healthier, more comfortable for people and he will elect to do that.

That is a problem in maintaining on site a relatively large quantity of these lenses so when the time for the operation comes you have not only the one that is needed, but perhaps a backup or two.

Mr. PEPPER. The doctor would own the little instrument, and sell it to the patient?

Mr. AQUAVELLA. No, it works in different ways in different settings. Sometimes the doctor performing that surgery in an office surgical suite, he would have it himself and implant it right into the eye.

Mr. PEPPER. Is there a division of the responsibility for the payment of the bill for the IOL?

Mr. AQUAVELLA. In different settings it is different. The responsibility for the payment might be to the physician in this instance.

Mr. PEPPER. In other words, Medicare by its own rules and regulation can simplify that?

Mr. AQUAVELLA. Yes. I think they can.

Mr. PEPPER. We can contact them.

That is the first thing—simplify the invoice.

And preferably, it ought to be the one individual invoice, it seems to me. The other thing is this very delicate matter about accepting medicare assignment. I wish the American Medical Association, including all of you who are in that broad term, could bring yourselves to accept the fees that are fixed by the Government of the United States.

The Government of the United States is no radical organization, certainly, at the present time, who has a disposition to be unfair to anybody that is doing a credible job, and every member of Congress, I imagine, has a doctor. He goes to see him sometime or another about something, or some member of his family does.

Every Member of Congress has doctors who are their friends, whom they respect. If Medicare were to be unfair to the doctors, something to say they are unfair, and as one of the gentleman said here today, it takes a lot of skill to perform a delicate operation like that, and I imagine there are certain dangers, certain risks involved in it, too, but it takes a lot of skill and responsibility to perform this important task and the doctor is entitled to be paid for his knowledge, his skill, whether it is his first time, like all other professional people but if we could ever simplify the process by getting the doctors to accept and give them the right of appeal, if they don't think they have been treated fairly, give them the right of appeal to some tribunal, give them a hearing, let the doctor say, or point out the skill required, the time involved and the delicacies of the operation and the like, we could simplify the whole process, and then we would relieve the beneficiary of having to pay his 20 percent or whatever it is in the matter.

Mr. AQUAVELLA. That is true, sir.

Mr. PEPPER. That is one thing that we hope the professions can move toward.

Mr. AQUAVELLA. The Inspector General mentioned it a little earlier, that is, a policy issue that is being looked at. There are two sides of that question, one is the question of utilization and many third party carriers, medicare or other large carriers, feel that a coinsurance payment on the part of the consumer, the ultimate consumer of the services, not the ultimate cost, whether it is 50 cents or $500, but that a significant coinsurance payment is important in controlling the method of utilization of those services in the system.

Mr. PEPPER. Let me interrupt you right there. That is applicable in the instance of where a patient goes in the hospital generally, you might say, and not on an emergency basis, and he might wait until next week.

Originally, I think Congress put the deductible into the medicare program to prevent a lot of people from going into the hospital to get a pleasant and very helpful weekend.

We have no objection to any reasonable medical care—remember, doctors put people in hospitals. They don't ordinarily go in by themselves. If the doctor won't certify that they ought to go in the hospital, they cannot go, as far as I am aware. But in a case like this, a man getting a cataract operation, I don't think he would go to get a cataract operation if he does not need it.

That is a delicate operation for a person to undergo. If that is the kind of case, you need that sort of deterrence.

Mr. AQUAVELLA. That is the direction that the Senator was going in when he discussed the possibility at one time in the future of bundling together all increments of the service-related to the cataract extraction or the hernia repair. That total payment then, one whole package, and make a judgment as to how those services should be utilized. Incentives might be able to prevent over-utilization of services and address the out-of-pocket expense issue which you just mentioned.

Mr. PEPPER. I wouldn't under any circumstances interfere with the professional discretion of the doctor. That is his job. I am a lawyer. I don't know anything about cataracts. I am not old enough to have one.

Mr. AQUAVELLA. They come only in the aged.

Mr. PEPPER. Remember this, the doctor sometimes yields to temptation, and we want to prevent him from putting that patient in the hospital and keeping him in the hospital, or having him go through some sort of a procedure that is not necessary, to get a fee.

We must protect against that. If that patient needs to be in a hospital because of one medical reason or another, he ought to go there and we wouldn't under any circumstances want to prevent that. But we have seen the instances of fraud and abuse of our people. People will abuse power and opportunity and, of course, we have to try to provide some protection. There ought to be, it seems to me, consultation and cooperation between your profession and the medicare people. Let's see if they can't work these things out fairly for everybody, and it may be that Congress should have a sort of a supervisory committee to sit in on the edge of the conference, just to sort of hear what is said and help, if it can. But all of these things can be solved without a lot of Government interference if we can reestablish the old American principles of integrity and honesty and put a noose on those who are willing to abuse those privileges.

Mr. AQUAVELLA. We will pledge to reinforce our meetings with HCFA. We already do it. We are in close consultation.

Dr. BETTMAN. If there is an appeal process, that you alluded to, Mr. Chairman, could I ask that it be, A, readily available, if necessary, and expedite it.

Mr. PEPPER. Yes.

Dr. BETTMAN. Sometimes in a large, necessarily large, bureaucratic sort of set up, there can be long delays and we don't want people waiting around for an awful long time with this sort of thing.

Mr. **Pepper**. We would want to accelerate it—to act expeditiously—and we would be willing to have a judge or anyone you had confidence in select a fair tribunal.

Dr. **Bettman**. Wonderful.

One other remark, if in any way we on the Ethics Committee of the academy can be of help, either for advice or action or whatever, please call on us. We would love to work with you.

Mr. **Pepper**. We are going to keep in touch with you about proposed legislation, submit it to you and ask for your comments on it. Ms. Oakar.

Ms. **Oakar**. This is a very interesting panel and it is good to see health providers interested in policing the issue of ethics, and very often peer pressure is terrific, not to do that kind of thing, and it is important. It is very, very good to see this panel.

Let me ask Mr. Smith, however, if you know of any instances whereby people with 20/20 vision, which I used to have until this year, I think, have gotten unnecessary surgery?

Mr. **Smith**. I am not personally aware of any specific case. No, I am not. I am sure it occurs but I am not aware of.

Ms. **Oakar**. Are you sure about that?

Mr. **Smith**. Seriously.

Ms. **Oakar**. OK. Let me ask the health providers themselves then and anybody who wants to answer this, whether you feel—first of all, we are not here to discourage people from having surgery that is helpful. Obviously with the innovations that have been made, it is a tremendous, wonderful procedure, whenever it is necessary.

In my own city of Cleveland, our space laboratory, the research center, has worked in conjunction with the medical community to see if they can come up with more innovative ideas about eye care, and it has just been fabulous to see this wonderful cooperation.

I think, and just want to make this statement, I think that if Congress could continue to feel, this is a good step in the right direction, that the medical community was really willing and interested in policing themselves, as obviously you are, from the testimony that you have given today, in your profession, your area, then you would see more cooperation from Congress in terms of trying to understand what your needs are. You mentioned, for example, that you pay $17,000 a year for insurance——

Mr. **Aquavella**. Million.

Dr. **Bettman**. $17 million.

Mr. **Aquavella**. That was his group.

Ms. **Oakar**. The group of physicians?

Mr. **Aquavella**. $17,000 for an ophthalmologist is not a low figure.

Probably in California——

Dr. **Bettman**. It varies enormously in different States and so on. I can't give you exact numbers, but sometimes it is pretty high.

Ms. **Oakar**. Right. Well, I think if we need more cooperation from the medical community to police themselves, investigate those surgeons who perform unnecessary surgery—and this has been done, not exclusively in this area, but many women feel that they have had lots of unnecessary surgery in some instances and I am sure men do, too. If we had more of an awareness of the high standards that you are maintaining for your members, and that you are willing to enforce them and, as you said, Doctor, publish the names and so forth, then I know we would welcome that—as we do anyway, but there wouldn't be this feeling that, oh, doctors don't want to do anything about their peers that are the bad apples, the few that there are, and then don't want to do anything about the high cost of the health care, and so on. I think that that is a perception that may or may not be true.

The fact that you came to this hearing willing to discuss the problems, and you are willing to police your own members, is a very wholesome, good thing to do and I congratulate you for doing that. I think in the future, we will see that we can continue to work closely together in arriving at some solutions for our people, because we have so many people that don't have any medical insurance period, and the elderly only have limited medical insurance, because medicare does not cover all their needs. Their out-of-pocket expense that the Senator mentioned, are a lot of money for them when they are only getting $350 a month. So I think this hearing can continue to develop a solution that everybody can work on together.

Dr. **Bettman**. You would be interested to know that in addition, we, the Ethic Committee, actually partly developed by an ophthalmologist from your own city of Cleveland, Dr. George Bush, and myself are developing a manual for the training of ethics to new ophthalmologists as soon as they enter the field so we are going to attempt to avoid some of these problems in the future.

At the present time, as you may or may not know, ophthalmology has instituted the national eye care program, and this is a project in which we are designating certain ophthalmologists throughout the country who are willing to take care of elderly people who are not able to pay for anything, and we are supporting that effort with our own money, and most of us have contributed $1,000 each to put this thing over.

Now, it has been a pilot project in three States up until now, but it shall be expanded, so that the entire country is covered, and this is an important development, and to the best of my knowledge, we are the only field in which this is being done, and believe me, we are exerting efforts and more shall be done.

Ms. **Oakar**. Well, I appreciate that, and I think the last project that you talked about is extremely commendable, and it is certainly worthy and I don't think anybody values one of their senses more than sight. Everyone wants to be able to see as well as possible.

That is one of the precious gifts of life, I suppose. It is good to have this kind of discussion.

Mr. **Aquavella**. You mentioned the issue of unnecessary surgery.

Ms. **Oakar**. I was not being exclusive in your area.

Mr. **Aquavella**. Oh, no, I know more about the question and how it might apply to the eyes than other fields. The problem with a cataract is that, the same level of actual opacity in the lens of the eye in three or four different individuals will create different levels of functional embarrassment. I say to patients with any kind of a cataract, how are you doing, how are you functioning? If they are able to read, and drive, even though they have a small problem, why, that is fine.

If, on the other hand, they are having difficulty functioning in their chosen environment—you are dealing then with things that are difficult to quantitate. We like to say 20/20, 20/40, 20/60. I have six examining rooms in my office and each one of them, my equipment will give a slightly different reading.

If you consider the illumination of the room, it is very, very difficult. We are striving to put together guidelines as to when, considering everything, it is appropriate to have cataract surgery.

Ms. OAKAR. Thank you very much.

Dr. BETTMAN. It is so difficult to put a number on these things. You have all driven a car with a windshield that has a little dust on it, a little dirt, and if one drives with the Sun behind you, you can see through that windshield very clearly, perhaps the equivalent of 20/20 vision, but if you are driving into the setting Sun, you can see next to nothing.

It is really a hazard and so it is with certain types of cataracts. Under certain conditions of illumination, like perhaps if they are in an ophthalmologist's office and the chart is illuminated and the rest of the room is fairly dim, they might read the 20/20, or 25 line, but if they go outside where the light is coming toward them, they may be so incapacitated, they might stumble on a curb, and so I know. I had that experience myself.

Mr. PEPPER. This last weekend I attended a conference in New York, the World Gerontological Conference, and many people were there from many nations of elderly age talking about the matter of health for the elderly, and the various systems from the various nations were being examined and the like.

I will be 85 years old the 8th of September, and the Lord has been mighty good to me in my life, but the great dream that I hope to see is in this blessed America of ours that we ought have the American experience with our sense of private enterprise, sense of rewarding merit, our sense of fairness to everybody, that somehow or another we can devise a medical sytem that will be fair to everybody that is a part of it, the providers and the beneficiaries, but the end result of which will be to assure that the most precious thing man can enjoy, the divine quality of life.

One of the most precious possessions that he can enjoy is life and health, and that nobody should be denied the benefit of what genius and science have provided, to extend life and benefit health, because he or she or a child does not have the money.

I call it good Americanism to help one another to enjoy those blessings.

On the 1st of May, a little bit ago, I had a meeting with about 20-odd people. We had six of the largest insurance companies in the United States who I think should have an increasing part in the building of such a system, and the head of the American Medical Association, the head of the American Hospital Association, and a whole lot of other people and we said to them, we are not here to sell you anything. We don't have any secrets in corners around here.

Nobody is taking notes. We are just here to talk about how we can help Americans to live longer and better, how we can devise a way it can all be made possible.

I think that is the greatest challenge facing our country, and even with all of our other problems, that means more to more people than any other challenge that we have facing our country today.

I think all of you have made a very valuable contribution this morning. I think Ms. Oakar, who is one of the most experienced and able people in this Congress, she will agree with me that we have never seen a group of witnesses better qualified, more dedicated, more valuable, and we thank you for your contribution.

We have one more witness to hear and that is Dr. Frank E. Young, Commissioner, U.S. Food and Drug Administration, Department of Health and Human Services, but we want to thank all of you in the warmest way for your valuable contribution.

Mr. PEPPER. Dr. Young, will you come forward, please?

Dr. Young, we are running a little late. We hope we didn't keep you too late.

PANEL THREE—THE FEDERAL AND IOL INDUSTRY RESPONSE: CONSISTING OF HON. FRANK E. YOUNG, M.D., PH.D., COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC, AND HON. CAROLYNE DAVIS, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

STATEMENT OF HON. FRANK E. YOUNG

Dr. YOUNG. I am particularly pleased to have the opportunity of sitting through the discussion, Senator, and to learn again of your great commitment to health. As a physician and former dean at a school of medicine and dentistry where Dr. Aquavella practiced it is a great pleasure to be with you.

I would like to summarize my statement.

This is a unique field that can best be expressed by looking at the problem with technological innovation and what has occurred to date.

When intraocular lenses were first developed after World War II, they were primitive devices. As experience was gathered during the fifties and sixties, it was realized that there was a problem facing the American people, the American medical profession and Congress as we tried to bring this technology onstream.

The problem was simply how to allow technical innovation while assuring patient safety and product effectiveness. As was stated by some of the witnesses, the cooperation between the ophthalmological community and Congress led to a solution which was to have reasonable availability for these devices, so that as the practice increased and the innovation increased, these devices could be available to the American people.

During this period of time, the change was from the anterior chamber type lens as you can see on the second chart there to a much more extensive use of the posterior lens.

This marked innovation was made possible, we feel, by the implementation of a flexible system of product approval. It was the FDA's charge on this type of legislation to innovate a mechanism whereby the reasonable availability could be brought into place.

This was done through an advisory committee consultation system at FDA, the development of IOL investigational status and the use of IOL core studies with a built on adjunct reporting system.

Mr. PEPPER. What is that little core in there? What is it?

Dr. YOUNG. A bit of plastic, sir, PMMA, which was discovered after World War II because one of the pioneering physicians observed that the fighter pilots in the British Air Force did not seem to have much inflammation around the fragments of plastic in the eye.

Its very basis was helped by an understanding that these were relatively inert materials, and in the eye, they might be able to be used as lens, and that led to the progressive development of these, and I would be happy to leave this with you, if you wish to have a survey of the placement and the different devices, and how they are used.

The very heart of the approval process was that we should be able to guarantee safety but also allow technological innovation at the same time.

The gentleman before me described the variety of shifts that occurred and the ability to move from an inpatient intense field to a field that was able to be done in the physician's office.

We have also, in looking at this and listening to your comments, looked back to see whether the presence of adjunctive studies versus core studies would have a differential price impact, and that is not the case, whether the device was implanted as part of a core study before the manufacturing, the premarket approval was in place or whether it was implanted under an adjunct study, there was no price differential.

Now we have evaluated further whether or not the adjunct studies are as necessary as they were 10 years ago, and we feel that they are no longer as necessary as they were earlier. We have under two circumstances not used adjunct studies in pediatric lenses, and in the soft lenses. We are reevaluating our procedures now to determine how we can reduce the adjunct studies, and merely use our premarket approval on the new and improved devices with a limited core study. FDA has attempted through its advisory committees and through its approval process to provide a mechanism whereby new products could be brought forward yet at the same time provide patient safety and product effectiveness.

That ends my formal statement, sir. I would be happy to answer any questions.

[The prepared statement of Dr. Young follows:]

PREPARED STATEMENT OF FRANK E. YOUNG, M.D., PH.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman; I welcome the opportunity to discuss the Food and Drug Administration's (FDA) role in assuring the safety and effectiveness of the intraocular lens (IOL), an important medical device that has helped hundreds of thousands of mostly older persons regain good eyesight after cataract surgery.

Following the surgical removal of the eye's natural lens, cataract patients and their physicians must decide which kind of artificial lens will help restore good visual focus and best meet the patient's needs. Many who choose eyeglasses must cope with poor peripheral vision or distorted images. Contact lenses partially overcome these difficulties, but many older people find them hard to handle and to maintain. For most patients, IOLs, which are surgically implanted in the eye, close to the normal position of the natural lens, can provide good vision without the distortion of eyeglasses or the handling difficulties of contacts.

BACKGROUND

The inspiration for IOLs first occurred to a British Royal Air Force Flight Surgeon, Dr. Harold Ridley, during World War II. British fighter pilots were sometimes injured when the cockpit covers of their planes were shattered by enemy fire, embedding fragments of the plastic in their eyes. Dr. Ridley was surprised to find that the fragments did not cause the usual inflammatory reaction that the body ordinarily employs as a defense mechanism against foreign objects. He concluded that this was due to the inert properties of the plastic. As an ophthalmologist, he saw the medical potential of such properties and in 1949 he surgically implanted the first IOL in the eye of a cataract patient.

There was some early use of IOLs in the United States but widespread interest did not begin until the late 1960's, after design and quality control improvements were developed in Europe. They were a promising technology, restoring near normal vision to thousands of elderly cataract patients. But they were also a relatively new technology for which no long-term safety and effectiveness data existed. There were reports of some serious complications with some implants being performed in the United States. In October and November 1975, FDA learned of 11 cases of severe eye infection in IOL patients. Vision was seriously impaired in all 11 cases and removal of the eye was required in 5 of the 11.

FDA was given authority to require clinical studies of IOLs, and other medical devices, under the Medical Device Amendments of 1976. Congress, in response to physicians' expressed fears of depriving patients of lenses and inhibiting technological improvements crafted the law to ensure that the lenses would continue to be "reasonably available" to investigators to implant while manufacturers collected safety and effectiveness data. The data collected under this authority would enable FDA to decide whether IOLs should be approved for general marketing. Therefore, IOLs presented FDA with a unique situation, whereby the Agency would have to balance the potential benefits of improved care for cataract patients and technological innovation against possible risk to larger numbers of persons in clinical trials.

In November 1977, FDA published a regulation outlining the conditions under which implantation of the lenses could continue. The Agency issued manufacturing guidelines to reduce the possibility that defective or bacterially contaminated lenses could be distributed to eye surgeons. Physicians implanting the lenses were required to monitor patients closely after IOL surgery and to report any complications periodically to the lens manufacturers. Patients were to be informed fully about the risks and benefits of IOLs before implantation.

CLINICAL INVESTIGATIONS

Clinical investigations, sponsored by a number of lens manufacturers, began in 1978. During those and subsequent investigations, several types of IOLs have been studied: anterior chamber lenses which are implanted in front of the iris; posterior chamber IOLs which are placed behind the iris; and Iris clip and iridocapsular lenses both of which are implanted even with the iris. Each class contained many models and styles.

To date, results of these investigations indicate that the rate of complications from implantation of lenses generally is not significantly higher than for cataract surgery without an implant. Complications of cataract surgery can include hemorrhage, clouding of the cornea, glaucoma, double vision, swelling, infection and retinal detachment. These problems are also associated with IOL implants, as are irritation or injury of the iris, inability to dilate the pupil, and lens dislocation.

When the first clinical studies began, about 10 percent of all cataract patients received an IOL. Today about 85 percent of the more than 600,000 cataract extractions per year in the United States include IOL implantation. Persistent complication rates comparable to those with cataract surgery alone, are about 1 to 2 percent for most IOLs, and about 90 percent of patients will have 20/40 or better vision. (A person with 20/40 vision can read letters on an eye chart from 20 feet away that a person with normal 20/20 eyesight can read from 40 feet away; 20/40 vision is good enough to get a driver's license in most States.) This level of vision is comparable to that achieved with glasses or contact lenses after cataract removal.

CORE AND ADJUNCT STUDIES

Our policy, in general, for conduct of clinical trials is to limit the number of patients to a population sufficient to develop data adequate to make valid scientific judgments on safety and effectiveness. We would normally oppose efforts to expand test patient populations for devices, especially higher risk devices, because patients might be exposed to unnecessary risks. In the case of IOLs, however, FDA responded to the directive of Congress in reports accompanying the Medical Device Amendments of 1976 to make them "reasonably available." In this instance, it would appear that, from a public health standpoint, the wider availability of the device has proved beneficial. Hundreds of thousands of cataract victims, most of whom are older persons, are enjoying better health and lifestyles today because of the clinical success of the IOL.

The investigational system which has made it possible to treat large numbers of patients is a dual system involving a small number of more intensively studied "core" patients and a larger number of less intensively followed "adjunct" patients. The system was developed by the Agency with expert advice from our Ophthalmic Devices Advisory Committee to conduct the initial clinical trials of IOLs. A similar dual reporting system previously had been used successfully by FDA in drug studies, and clinical investigators on our Advisory Panel were familiar with its use. Both core and adjunct investigators were, and are, required to report to the sponsor certain types of adverse reactions, such as hypopyon, an inflammatory reaction which could signal a problem with the IOL. These specified adverse reactions must be evaluated by the firm sponsoring the study and forwarded to FDA within five days of receipt.

Both core and adjunct studies must meet FDA's strict criteria for clinical investigations. Before an investigation can begin, a sponsor—usually a manufacturer—must submit a detailed plan for the study in the form of an investigational device exemption (IDE) application. FDA carefully reviews this plan. The Agency also checks the design of the lens, the manufacturing controls that the sponsor has established, and the materials that the manufacturer intends to use, to insure that there are no toxicological problems. Other aspects of the investigations are checked to insure that there are no microbiological problems.

The Agency rejects applications that fail to meet our IDE criteria. For example, we do not allow implantation of anterior chamber IOL designs that could vault forward to hit corneal endothelium which does not regenerate in humans. We do not allow implantation of IOLs that do not have adequate testing for residues that can provoke inflammation. Similarly, we do not permit implantation where there may be problems with instability of design.

Our IDE application review process requires specifications on leachable materials and animal tests on all new materials. We also require evidence to assure that the sterilizer systems meet strict criteria for implant materials.

Once an IDE application is approved the sponsor is required to carefully monitor the study throughout its duration. A properly executed clinical trial is, of course, essential to provide the valid scientific evidence for a judgment of safety and effectiveness. FDA requires that the firm specify a monitor for the study, keep an adequate schedule for review of the clinical data by the monitor, limit the number of investigators and patients in the early stages of the study, and report adverse reactions within 5 days of when they learn of them. An annual report to FDA is required in addition to this internal review.

Based on the results of "core" and "adjunct" investigational studies, the first IOL premarket approval (PMA) application was approved in December 1981. Since that time FDA has approved 12 other PMA applications and 28 supplemental PMAs. These approvals cover 76 different IOL models from 7 different manufacturers.

Many IOLs remain in investigational status. As of May 31, 1985, there were 82 investigational device exemptions for IOLs. This represents 313 different IOL models for core investigations and 531 different models for adjunct studies. In response to a recent questionnaire from you, Mr. Chairman, we have provided the Committee with these data and other information on our IOL activities and policies.

TECHNOLOGICAL ADVANCES

The large number of ongoing investigational studies reflects the rapid pace of developments in IOL technology. The most significant development has been the widespread adoption of microsurgical techniques and of extracapsular cataract extraction (ECCE), in which the posterior capsule of the lens remains in place. Results following ECCE and implantation of a posterior chamber IOL have been better than the results of other procedures. Currently we estimate that 85 percent of U. S. implantations are ECCE with a posterior chamber IOL; 10–15 percent are anterior chamber lenses; less than 1 percent are iris-fixation or iridocapsular lenses, and well less than 1 percent are beginning studies of new "soft" IOL materials.

Other examples of emerging IOL technological advances that are being studied include:

Modifications for surgical techniques, such as positioning holes and locating hooks;

Addition of a "laser ridge" on the posterior surface of a posterior chamber lens to reduce pitting of the IOL when the YAG laser is used to perform posterior capsotomy (or surgery to open the posterior capsule of the lens);

Modifications for small incision surgery, to reduce astigmatism;

Inclusion of ultraviolet-light absorbing materials to reduce retinal exposure;

Changes in optical shape factors to reduce optical aberation, and, most recently, studies in very early stages of "soft" materials.

POST MARKETING SURVEILLANCE

While it is important that we continue to provide an environment conducive to the development of improved lenses and surgical techniques, it is equally important that we keep close track of possible problems with those lenses that FDA has approved for marketing. To keep informed of possible problems with IOLs and other medical devices, the Agency has developed the Device Experience Network (DEN) complaint system and the Medical Device Reporting (MDR) system. Since 1977, FDA has received only 54 complaints on IOLs through the DEN system. Even though DEN is a voluntary reporting system, this is a remarkably low number considering the hundreds of thousands of implants annually. Since December 1984, when the MDR—a mandatory reporting system—became effective, 28 reports have been reported through that system. Manufacturers are also required to review unexpected adverse reactions for approved IOLs and report on those to FDA in their annual reports.

As I noted earlier, in addition to these reports, FDA receives unexpected adverse reaction reports for IOLs being studied in clinical trials. We estimate that these unexpected adverse reactions occur at a rate of considerably less than 1 percent of total implants.

POLICY REVIEW

Although the safety record of both marketed and investigational IOLs has been a very good one, we are reviewing our policy on adjunct studies. Because a large number of IOL models have been or soon will be granted PMA approval and therefore will be widely available, the Congressional directive that FDA assure that IOLs are "reasonably available" has or will soon be met. For this reason, FDA is considering: (a) whether investigations of new IOLs should be restricted to core patients; (b) whether and how additional patients may be entered into a study after submission of a PMA to FDA; and (c) what should be done about ongoing investigations that include adjunct studies.

CONCLUSION

In summary, Mr. Chairman, since 1978, under FDA's oversight, IOLs have benefited hundreds of thousands of mostly elderly cataract patients. FDA will continue to review closely the investigational studies of developing IOLs and to monitor for possible problems with those lenses that have been approved for marketing. We will also review our policy on the continued need for "adjunct" studies in light of the number of approved lenses now available to cataract patients and their ophthalmologists.

This concludes my statement, Mr. Chairman. If you or members of the Subcommittee have any questions, I will be happy to answer them.

Mr. Pepper. We had hoped that Hon. Carolyne K. Davis, Administrator of the Health Care Financing Administration would be our next witness, but she was unable to attend. However, she did reply to written questions and ask that they be included in the hearing record. Without objection, those questions and answers are submitted for the record at this time.

[The material submitted for the record by Chairman Pepper follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES,
HEALTH CARE FINANCING ADMINISTRATION,
Washington, DC, July 18, 1985.

Hon. CLAUDE PEPPER,
Chairman, Subcommittee on Health and Long-Term Care, Select Committee on Aging, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to conversations with subcommittee staff, enclosed is information, provided earlier to you, which we request be included in the record of the July 17 hearing on intraocular lenses.

Sincerely yours,

CAROLYNE K. DAVIS, Ph.D.

Enclosure.

Question. Please provide the number of procedures and costs of cataract surgery for the last four years and projections for the next years — broken down (or explanations of why breakdown is not possible) by hospital inpatient (DRG and non-DRG); hospital outpatient; freestanding ambulatory surgical centers; in physicians offices; and totals.

Answer. Medicare information by procedure for cataract surgery is currently available for inpatient hospital care only. Information by procedure for physicians' services (recently collected for the first time for 1983 services) is not yet available. Data on procedures for outpatient hospital services are not collected.

Date for inpatient hospital procedures for DRG 039, Lens Procedure, (includes all cataract surgery) are available for calendar year 1981 and fiscal year 1984.

	Number of cases	Average charge per case
DRG 039:		
Calendar year 1981	332,000	$1,639
Fiscal year 1984	409,000	2,344

Please note these limitations of the data:

a. Data for fiscal year 1984 is still incomplete due to lags in submissions to HCFA's central statistical processing areas;

b. Average costs for surgical procedures are not available for 1984. However, we have provided average charges for DRG 039 which encompasses all cataract surgical procedures for both 1981 and 1984.

c. Similar data for 1982 and 1983 are not available.

Question. What is HCFA's policy on outpatient cataract surgery and what steps you have taken to implement the policy?

Answer. Outpatient cataract surgery is covered under Medicare. In recent months, attention has focused on outpatient cataract surgery because more and more Utilization and Quality Control Peer Review Organizations (PROs) are screening claims for cataract surgery to assure that they are performed in the appropriate setting. HCFA is in agreement with the PRO review of cataract surgery and closely monitors all of their objectives, activities and the effect on Medicare beneficiaries.

As you know, Medicare review requirements are established by local PROs. The purpose of the PRO program is to assure that the care provided to Medicare patients is medically necessary, is provided in the appropriate setting, and meets professionally accepted standards of patient care quality. In that regard, each PRO must meet certain objectives designed to provide that assurance. One of those objectives is to reduce hospital admissions for elective procedures that could be performed effectively, and with adequate assurance of patient safety, in an ambulatory surgical center or on an outpatient basis.

Medical authorities agree that many lens procedures which are now performed on Medicare patients on an impatient basis can be safely, effectively, and more economically performed on an ambulatory basis. As a result, over 30 PROs have an objective to shift lens procedures from the inpatient setting to the outpatient setting where that setting is appropriate.

Screening criteria are developed by PRO physicians. They are used by the PRO to approve payment for cases which clearly meet accepted standards and to refer questionable cases to physician reviewers. The PRO physician reviewers, who are actively practicing physicians in the State, make their determinations based on their own knowledge, experience, training, and on discussions with the attending physician for the case being reviewed. In making a determination about the appropriateness of inpatient versus outpatient cataract surgery, the PRO physician reviewer must evaluate all the circumstances which may impact on the medical care in a given case. This involves taking into consideration the medical condition of the patient before surgery, as well as the needs of the patient following surgery and other extenuating circumstances. The screening criteria, however, only apply to elective surgery. Patients with emergencies are always admitted whether or not the PRO has performed its review.

When a denial is made, the PRO program provides a comprehensive reconsideration and appeal process to protect the interest of Medicare patients. The patient, his representative, the hospital, or physician has the right to request a reconsideration if dissatisfied with a PRO's decision.

Question. What is policy or whether all carriers should use a uniform approach to determining how much to pay for intraocular lens (IOL's) charges--please briefly outline current carrier practices in reimbursing the IOL's?

Answer. Payment for the intraocular lens (IOL) is not part of the ambulatory surgical center (ASC) facility rate, but rather, is made under the prosthetic device provision. Carriers do have a uniform approach to payment for IOLs which involves application of the Medicare program's reasonable charge principles. These principles involve the calculation of a customary charge and a prevailing charge based on actual charge data of physicians or suppliers. In addition, carriers have discretion to make inherent reasonableness determinations in setting the reimbursement rate for IOLs.

Question. Please describe actions taken by HCFA and its contractors to determine how IOL cost savings are passed on to Medicare.

Answer. A HCFA investigation of available data showed that the vast majority of cataract surgery is performed on either an inpatient or outpatient hospital basis. The trend is toward one day inpatient surgical stays. Payment for intraocular lenses is not an issue in these instances. The cost of lenses is included in the DRG for inpatient cataract surgery. When the hospital provides the lenses for outpatient surgery, cost reimbursement is the basis of payment. Although the physician could provide the lenses for outpatient surgery and bill on a reasonable charge basis, this is rarely done. Thus, there is little potential for savings through administrative action by HCFA or its contractors.

Question. Please provide HCFA views on current reasonableness of surgeon fees for routine cataract/IOL surgery.

Answer. There is no official HCFA position on the reasonableness of surgeon fees for routine cataract surgery. However, there is concern that certain procedures have become overpriced in relation to the time, effort and risk involved due to the development of new procedures and technologies. HCFA will be contracting for studies to develop a relative value scale on the cost of producing physician services for possible use under current legislative authority or as part of overall physician reimbursement reform.

Question. What are HCFA's views on need for assistant surgeons in routine cataract surgery and reasonableness of their fees?

Answer. HCFA's policy states that the use of the services of an assistant surgeon in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community. The reasonable charge for the services of an assistant surgeon may not exceed 20 percent of the prevailing charge, as adjusted by the economic index, for the surgical procedure. This limitation applies to reasonable and necessary services of assistant surgeons in all settings.

Question. What are HCFA's views on the reasonableness of various outpatient facility fees and need for a new survey to update data?

Answer. The prospective rates of payment for ASC facility services now in use were established in 1982 based on a relatively small sample of the operating costs and charges for services of ASCs in existence at the time. While we believe that the rates are generally appropriate, we also believe there is reason to review the rates to determine whether any changes are indicated by current operating cost data and other fiscal information. HCFA is developing a survey to obtain cost data from all participating ASCs in order to do the review.

Question. What are HCFA's views on the current practices of some hospitals and ambulatory surgery centers in advertising "no cost" (to the beneficiary) cataract surgery?

Answer. Nothing in those portions of the Medicare law and regulations which deal with civil rather than criminal matters and for which HCFA is responsible precludes a hospital from routinely waiving payment of deductible and coinsurance amounts for hospital services. Such waiver precludes Medicare payment for the waived deductible and coinsurance as a bad debt but does not otherwise reduce Medicare payments to the hospital. The Office of Inspector General (OIG), however, views such waiver as a possible criminal violation of the bribes, kickbacks, and rebates provisions of section 1877(b) of the Social Security Act. The OIG is currently working toward resolution of this issue with the Department of Justice.

Under the law (section 1833 of the Social Security Act), payments from ASC facility services are not subject to deductible and coinsurance. Also, the payments for the related surgical services by the physician are not subject to the deductible and coinsurance if the physician accepts assignment. (This would also be true if the same surgical services were performed by the physician on an outpatient basis in a hospital.) Thus, no question of a possible civil or criminal violation should arise regarding the provision of "no cost" cataract surgery to beneficiaries in an ASC where the physician accepts assignment.

Mr. PEPPER. Ms. Oakar.

Ms. OAKAR. Thank you, Mr. Chairman.

Thank you, Doctor, for being here.

I want to see if I understand this correctly, because you brought up the subject of studies.

Now, just so the public understands what is taking place here, we have these adjunct studies that are taking place.

Dr. YOUNG. Yes.

Ms. OAKAR. Do you pay doctors for doing this?

Dr. YOUNG. FDA does not pay physicians at all to do these studies. They are sponsored by the manufacturer. The FDA requires through its procedures that when a device is manufactured, an investigational new device exemption, the first portion of the manufacturer's submission to FDA is the submission for an investigational device exemption.

In the 107 IOL's that I have summarized there, you can see, this is an historical record of the action of FDA: 70 were approved and 19 were not approved, 16 were voluntarily withdrawn and two were withdrawn by FDA.

After an investigational device exemption is given, the manufacturer then proceeds on a core study of 500 patients in which they must follow the patients during the first year with four examinations and follow them carefully to determine that there are no adverse effects with this device.

During the time that the core studies are going on, in order to get further experience adjunct studies can also be taken, but the results of these adjunct studies must be reported so if there are any complications we would know about this at FDA.

Ms. OAKAR. You said the use of this kind of plastic—the senator held up the type of lens it is—it has been developed since World War II?

Dr. YOUNG. Yes.

Ms. OAKAR. It is my understanding that there have been over a million of these IOL's that have been implanted in people's eyes, and I assume many successfully. Is that correct?

Dr. YOUNG. Yes.

Ms. **Oakar**. You also stated that in the process which, for example, some of us have been somewhat critical of FDA in the past, we had some hearings on that in the past, but I will not get into other areas. But in the process, it is the manufacturer who pays the physician and in this adjunct study approach?

Dr. **Young**. That is correct.

Ms. **Oakar**. There is wherein some of the kickback and abuse, I think, takes place. You have been studying whether or not to continue this process since 1980 at least, that I know of.

How long does the consumer have to wait until we finally give the go-ahead? In other words, FDA has not approved technically some of what is going on here, and it seems reasonable to assume that much of what has been done by these experienced physicians, et cetera, is safe and effective. We have had a million implants or more. How long do we have to wait for FDA to act on this?

Indirectly you are sort of approving this kickback kind of approach. The committee report is really illuminating about this.

Hopefully you do not really want to do that, but how long do you think we ought to wait until you approve this? We have been waiting for other things, but how about this one?

Dr. **Young**. I would submit that we are not culpable in this scheme at all.

We also would have to rely on the manufacturer who really determines the degree of fee that is provided, if any, and how the core study is paid for.

Ms. **Oakar**. I introduced legislation to close up these loopholes. I don't think you really need legislation, but since you do not want to close them up, what I am trying through my legislation is to force you to act. I hate to do it that way, but that is the only way we are going to get something done.

You have the manufacturers in effect paying physicians every time they use one of their lenses, whatever, and I can understand now why there are some physicians who kind of like to keep this going on, not all. We heard marvelous ethical physicians testify today; but when do you think you are going to put some use to these studies and get on with the show of approving it or disapproval or move a little?

Dr. **Young**. We have approved 13 original premarket approvals and 28 supplements. Currently there are awaiting 17 additional applications and 46 supplements for a total of 63.

We have approved the premarket applications, because it is not the same standard lens.

I must clearly emphasize, as I am sure the ophthalmologists would, that there have been great improvements in the total intraocular lens over this period of time. Each time a major change or a minor change occurs, our statutes require us to examine these changes so that there are not medical complications.

Ms. **Oakar**. One of the things in my legislation is, we try to have post studies after the use of a product being used, whether it was a medical drug, this type of lens, that FDA would be mandated to continue the research, but see, here is the problem.

You are allowing the burden of proof to be on the manufacturers who pay the physicians who then give you their studies, and what you are doing—and I am telling you and I think you know that is the criticism of the committee—is giving them a legal vehicle for those few who would engage in these kickbacks.

Dr. YOUNG. Sure.

Ms. OAKAR. I think FDA ought to get on with the show. We have been disappointed in FDA in other ways. I cannot tell you how strongly I feel about what the Secretary is doing about the dyes that everybody knows produce cancer. You have made some recommendations, but the consumer is still getting all these awful products on the market with no guidelines. In addition, we have diet drugs on the market over the counter that are terrible for people. FDA does not want to act on this. They have been studying it since 1939.

I think you are part of the reason, whether it is intentional or not, that we have the situation that the chairman and his extraordinarily able staff have exposed in this committee report. If you do not agree with that analysis in the report you ought to give your response to it, because it seems to me by allowing over a million performances of surgery and still no final approval that somewhere along the line there is something going on there. We should institute laws to forbid former FDA people from investigating FDA approvals. It is like the military. When they leave the military, some few go into defense contracting, and then they come back and it is a vicious circle.

Well, this is happening with your agency, and something is wrong about having over a million of these types of surgeries performed and no final approval for so many of these, and the physician can get a manufacturer's fee for using that product.

Come on. One and one are two, and the committee knows this and I think you ought to cooperate and get on with approving it, disapproving it or what have you.

Dr. YOUNG. May I please state clearly, since you asked about the adjunct studies, what FDA intends to do. FDA is in the process currently of reducing the adjunct studies. We feel that now is the time that that can be undertaken, and we feel that before the end of this year we will have guidelines in place for a major reduction, but I also submit that it is not a static field.

The posterior lens did not come into place until 1980, and many of the studies that have been done have dealt with the subsequent technology, the introduction of UV opaque lenses, and the FDA has the responsibility of assuring safety and we cannot allow lenses to rush on the market.

Ms. OAKAR. Well, look, you have approved 103,000 IOL's that were implanted, but there are still 710,000 under investigation, so it is 2½ to 1. We do not want you to do anything or put your stamp of approval on something that is not safe and effective, but the public has a right to know that the manufacturers pay physicians, if they are engaged in these little old studies, every time they use one of their products that have not technically been approved. That is wherein, I think, some of the fraud and abuse and kickbacks take place. So that is my comment about it.

Maybe in writing you would like to respond to the committee report on it, and I just think the FDA in many areas could do a much better job. I feel so strongly that you are supposed to be protecting the consumer and at the same time not being married to the manufacturer, and that is part of the problem, I think.

Thank you very much.

Mr. PEPPER. Thank you, Ms. Oakar.

Ms. Oakar expresses a matter of grave concern that we have about this matter, Dr. Young.

In the first place, who set up this adjunct program under which the companies pay these doctors an additional fee for purportedly giving them some sort of report? Who did it?

Dr. YOUNG. FDA set up the core studies and the adjunct studies in response to the reasonable availability criterion. The device legislation differs from the drug legislation in one important area, Senator.

In the device legislation, there is a possibility for the manufacturer to obtain a reasonable return on the product during the time that it is in the approval process and that is part of the medical device amendment that was established by Congress in 1976.

In regard to the core versus adjunct study, this was FDA's response to attempts to make a reasonable number of these lenses available during the time that they were being introduced.

Mr. PEPPER. Excuse me. I have no objection whatsoever to the lenses being available. I think they should be available, and it has been a godsend to many people with sight problems that they are available; but under the authority that you have to permit the use of these IOL's it would seem to me that the company would not have to pay the doctor who is permitted to use that product. You could require that doctor as a condition of use to make a report about what experience he has had in the use of these instruments and also send a copy of that report to you.

In other words, why should the manufacturer—for example, if there is information that would lead to the improvement of the instrument, why, there is no reason why the doctor could not send a dual report to the FDA and to the manufacturer how his product worked, and what experience the doctor had with the use of it. You could require that as a condition to allow them to use it, without the company having to pay them anything.

They do not conduct any separate investigation. I imagine they implant this instrument, see how it works and see what reaction the patient may get from it and the like. I imagine that the only information that they transmit to the manufacturer is information incident to the experience they had in the implant of the IOL. Why do they have to be paid by the manufacturer for telling him what experience they had in the use of his product, especially when they have been permitted to use it?

Dr. YOUNG. We do not require the payment in any way.

Mr. PEPPER. Excuse me. One other thing. First is whether the manufacturer ought to be permitted to pay the doctor anything for doing that. He charges a good fee apparently, from the evidence we have, for his work and he is entitled to a fair fee. Now, why does he have to come along and get another payment on the side, as it were, for an instrument, the little device? Well, are you monitoring the amounts that the companies are paying those doctors and have you approved the amounts that they pay?

Dr. **Young**. We do not approve the amounts that are paid nor do we require that payment be made.

Mr. **Pepper**. Nobody is approving them.

Dr. **Young**. Absolutely, no one does.

Mr. **Pepper**. They can call it an investigation fee.

Dr. **Young**. That is the company's decision, not FDA's, sir.

Mr. **Pepper**. Do you not have control over the process?

Dr. **Young**. No, we do not.

Mr. **Pepper**. You have the control over whether to use that product or not, and you can condition its use.

Dr. **Young**. Let me ask counsel, if I could, to respond to that, because I do not know whether we have the legal authority to be able to require nonpayment to the physician on the part of the company.

Mr. **Scarlett**. It is my understanding that the physician using the IOL in an adjunct study does provide information on the experience the doctor has with the device. That is a species of investigational information. It is absolutely standard practice that companies pay doctors for conducting investigations.

Mr. **Pepper**. What kind of investigation do they make other than telling their experience?

Mr. **Scarlett**. Congressman, I do not know. Our legal authority extends to prohibiting the commercialization of the device. If, in fact, what the company is doing is paying the doctor a fee to use the device rather than paying the doctor a fee to conduct an investigation, that is not legal. That is something Mr. Kusserow can look into. It is not permitted. We are not permitting it.

Mr. **Pepper**. What is the excuse for these payments then?

Mr. **Scarlett**. The reason, and I do not know whether it is an excuse or a reason, because I have not looked into it, is that the doctor is being required as a condition to the investigational use of the device under the adjunct investigational rules to provide certain information, his experience with the device, to the company. In exchange for that the doctor is paid an amount of money.

Mr. **Pepper**. They are paid a fee, and it may be too high.

Mr. **Scarlett**. Then it is not legal. Mr. Kusserow could take some form of action under those circumstances.

Mr. **Pepper**. Did you say the companies do not pay the doctors any fee for investigation?

Mr. **Scarlett**. No, I said the opposite.

Mr. **Pepper**. Well, that is what I thought. I said what investigation do they conduct other than making a report of their experience?

Mr. **Scarlett**. I will ask those people who are familiar with that area to provide the answer. I do not know.

Mr. **Pepper**. In other words, the FDA, which permits the use of the device, does not know what kind of payments are being made by the companies. They do not know what kind of reports are being made by the doctors.

Mr. **Scarlett**. Mr. Chairman, I did not say any of that.

Mr. **Pepper**. Just a minute. So far as I can understand, the companies have carte blanche to pay whatever they want to pay as a supplemental fee to the doctor for the use of their device?

Mr. **Scarlett**. That is not true.

Mr. PEPPER. And nobody so far is checking it or even knows how much it is?

Mr. SCARLETT. That is not a correct statement.

Mr. PEPPER. All right. What is a correct statement?

Mr. SCARLETT. That FDA does not have a fee schedule. We do not have specific payments that doctors are entitled to receive, that companies are permitted to give.

Mr. PEPPER. You do not know how much they are being paid?

Mr. SCARLETT. That is true enough.

Mr. PEPPER. OK.

Mr. SCARLETT. We do not know. If that is the point you are trying to make, we do not know.

Dr. YOUNG. I do not believe that the Government has a figure on how much each physician using an investigational device is paid.

Mr. PEPPER. But you have authority over there, do you not, Dr. Young?

Dr. YOUNG. Senator, I believe that we have the authority to require that the information come in to us.

Mr. PEPPER. Why do you not look into this matter, Doctor, and find out what the facts are and see to it that whatever is right be done and whatever is wrong be stopped.

Dr. YOUNG. I certainly applaud that, Senator.

I think the problem that we have in addressing this is that it was not given to us by the congressional authorization, to my knowledge, to fix any of the fee structure that the companies might charge. That is basically the problem. We fix the information that is required, but we do not have authority over the fee structure and any arrangements that the companies make.

I agree that it is wrong and despicable to have kickbacks, fraud and abuse of the Medicare system, and I vigorously support your main purpose in this hearing. This is one of the reasons in our development of the soft lens approach we did not have adjunct studies nor do we have them in pediatric and we are closing adjunct studies down; but even if we did, I would imagine that there would be some compensation for the physicians involved in the core studies.

We do not have that authority to regulate that either, as far as the fees given to the physicians.

Mr. SCARLETT. The other example of kickbacks that was cited in this hearing had to do with pacemakers which were not under an investigational structure, and it would not have made any difference in that situation whether FDA had any involvement at all, because they were paying kickbacks. If we eliminated this, Mr. Chairman, there would be the same potential for companies to pay kickbacks, the same incentive for them to pay kickbacks and provide inducements for physicians to use their products.

Mr. PEPPER. This is just a cloak?

Mr. SCARLETT. It makes it a little easier for them. If they were not using it, they would find some other way to do it.

Mr. PEPPER. Anybody connected with the Government give your agency the authority to do what we were just saying?

Dr. YOUNG. It could be with additional congressional authority, in my opinion. I do not believe that our authority that we have at present allows us to do that.

As a former dean of a medical school, I strongly support your stand and others on medical ethics. This is a very difficult situation and something that just cannot be tolerated, but we are in a very important range of technological advancement and somehow we must still have studies. If there are 700,000 lenses implanted a year, a simple statement was made earlier that only 1 to 2 percent have complications. Well, that is 14,000 people; and if there were appropriate investigations to even cut that in half, that is 7,000 more senior citizens that would have a better lens. So there does need to be change in product, and we have to balance off the legitimate investigation with fraud and abuse, and I would be delighted to work with you on that.

Mr. PEPPER. We would not object to any honest and fair and intelligent investigation. We are talking about a general practice which looks like an abuse of a program on the part of a manufacturer, and there is no public supervision of what they are doing. They can almost exercise carte blanche in giving these doctors any amount of money they want to; and I dare say you will find, if somebody should investigate it, that the doctors that buy the most of that kind of an IOL, they get the most money for investigation in a lot of cases, not all of them.

Would the Secretary of Health and Human Services have authority to give you this power?

Dr. YOUNG. I do not believe so at this point.

Mr. PEPPER. You look into the legislative aspects of it.

Dr. YOUNG. Mr. Kusserow's request for authority and your very strong support of his additional authority would provide some of that. Mr. Benson on my left is deputy director of the Center for Devices and Radiological Health.

Jim, do you have any knowledge?

Mr. PEPPER. Doctor, make it brief. We have to vacate this room.

Mr. BENSON. I do not think we have the authority to control the payment for investigations.

Mr. PEPPER. Thank you very much. We will see if we cannot give you that kind of authority because it looks like it would be in the public interest. Do you not think it would be in the public interest if you had authority?

Dr. YOUNG. If we had the authority, we could aid in decreasing some of this type of problem.

Mr. PEPPER. Thank you very much for your excellent testimony and your kindness in coming and helping us today. Thank you.

APPENDIX 1

CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

A REPORT

By The

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

Of The

SELECT COMMITTEE ON AGING

July 19, 1985

PREFACE

In 1983, the Subcommittee on Health and Long-Term Care of the U.S. House Select Committee on Aging undertook the first Congressional investigation of cataract surgery in the United States. This report is the summary of the Subcommittee's findings. In sum, the Subcommittee found that there is widespread fraud, waste, and abuse in cataract surgery — the most frequently reimbursed major surgical procedure in the United States today.

The Subcommittee concluded that over $2 billion that we will spend in 1985 for cataract surgery will be lost to fraud, waste, and abuse, and that this surgical procedure, from the taxpayer's perspective, is an unmitigated disaster. In order that the more than 1,000,000 older Americans might reap the benefits of vision attributed to this uncontested miraculous procedure, the Subcommittee urges immediate reform measures to address this hidden, yet prevalent problem.

The Chairman's report was prepared at the direction of Kathleen Gardner Cravedi, Staff Director of the Subcommittee and written by her and Peter Reinecke, Research Director, Glen Stettin, National Health Policy fellow, Medical College of Pennsylvania, Melanie Modlin, Deputy Staff Director, Ronald Schwartz, Office of the Inspector General for the Department of Health and Human Services, and Catharine Wilson, intern, Duke University who also tabulated, analyzed and summarized information supplied the Subcommittee by ophthalmologists, the industry and others. Eve Subrin, intern, Cornell University graduate, Liz Gatti, intern, Duke University, Bob Joy, detail, U.S. Postal Service, and Hal Wallach, detail, U.S. General Accounting Office, also provided valuable assistance to the Subcommittee — without whom this report would not be possible. The Subcommittee also recognizes the consulting services of Bill Halamandaris and Jay Constantine whose policy insights were invaluable from the inception of this Subcommittee investigation. The Subcommittee also wishes to commend numerous others whose counsel during the investigation helped balance the many issues explored.

I commend this report to all those concerned with preventing the abuses we uncovered. I hope it will lead this Nation to much needed reform.

Claude Pepper, Chairman

EXECUTIVE SUMMARY

CATARACT SURGERY: FRAUD, WASTE, AND ABUSE

In 1982, a Congressional inquiry revealed massive, fraud, waste, and abuse in the purchase and use of pacemakers in the Medicare program. Investigators uncovered a pervasive, industry-wide practice of kickback schemes, overutilization and profiteering in the pacemaker industry at the expense of Medicare and the taxpayer.

During the course of the pacemaker investigation, a representative of one of the manufacturers told a consultant to the Committee, then posing as a prospective purchaser for a California hospital, that these practices were not limited to the sale and use of pacemakers. "In addition, he said,"we sell intraocular lenses, heart valves, orthopedic devices, and health products for seniors. We have great flexibility. We (the distributor) give. They (the manufacturer) gives. We can even work out a package deal. We can arrange at least a 15% discount on VA approved prices." (The Veterans Administration purchases pacemakers, lenses and other medical equipment at a competitive bid process which commonly runs 15-20% lower than Medicare's payments for the same products.)

The salesmen went on to indicate that intraocular lenses in particular were a profitable product, saying anyone, including the hospital administrator, could learn how to perform the implant procedure and that it could be done on an outpatient basis or "almost anywhere."

When he learned of this conversation in 1983, Chairman Pepper instructed the Subcommittee to undertake a thorough investigation of cataract surgery and the use of intraocular lenses (IOLs) in the United States. This report is the result of that activity.

During this investigation, the Subcommittee undertook the following steps:

- Collected, reviewed and tabulated correspondence and case histories received by the Subcommittee relating to cataract surgery since 1983.
- Reviewed all hearings and reports on fraud and abuse in the Medicare program by Congressional Committees and administrative agencies.
- Prepared and sent a questionnaire to a statistically valid random sample of ophthalmologists in the United States at the Chairman's request. The responses to these questions were tabulated and appear later in this report. The questionnaire can be found in Appendix A of this report.
- Prepared and sent a questionnaire to all IOL manufacturers on file with the U.S. Food and Drug Administration. The responses to these questions were tabulated and appear later in this paper. The questionnaire can be found in Appendix B.
- Conducted telephone surveys with numerous IOL representatives, associations representing ophthalmologists, health industry representatives and concerned doctors.
- Reviewed all books, periodicals, and newspaper references to cataract surgery and Medicare reimbursement policies on file with the Library of Congress.
- Prepared and sent questionnaires to the U.S. Food and Drug Administration and the Health Care Financing Administration. The responses to these questions were incorporated into this report. The questionnaires can be found in Appendices C and D repsectively.
- Requested and obtained a staff member from the Office of the Inspector General of the United States, Department of Health and Human Services, to assist the Subcommittee in its investigation.
- Called upon the Office of the Inspector General to undertake an investigation into the billing and reimbursement practices for cataract surgery in the United States.
- Called upon the General Accounting Office to conduct a review of Medicare reimbursement practices to determine regionally what Medicare pays for cataract surgery.

- Interviewed numerous sales representatives for the IOL industry, ophthalmologists, association representatives, enforcement officials, health and medical experts.

The Subcommittee found that cataract surgery is the most frequently reimbursed major surgical procedure reimbursed by the Medicare program today. Intraocular lenses (IOLs), the replacement of choice following cataract surgery, will be implanted in 1 million of the 1.2 million people who will have cataract surgery in 1985. The total cost of these cataract procedures will exceed $3.5 billion. $3.03 billion of that total will be paid for by Medicare. The Subcommittee found that there is reason to question the necessity or validity of half of that total. 50 cents of every dollar Medicare pays for this procedure is lost either to fraud, waste, or abuse. The factors forcing this conclusion are as follows.

Cataract surgery, which in 1981 required a 3-day stay in a hospital, now requires a 3-hour visit to a hospital on an outpatient basis. About 70% of all cataract surgery is performed today in the outpatient setting of a hospital. Improved surgical techniques and hospital cost containment have contributed largely to the shift from the hospital to the outpatient setting for cataract surgery. Intuitively, one would think that savings would accrue to the Medicare program by eliminating hospital stays and the attendant services which accompany the stay. This has not been the case. Medicare pays no less than $2400 for cataract surgery performed in the hospital where the costs are controlled by the new DRG system. When the same procedure is performed in the same hospital on an outpatient basis, Medicare is paying several times this amount — as much as $5700 — for using only three hours of hospital resources. While the DRG system was intended to reduce Medicare costs by putting a limit on the amount paid for services provided in a hospital, the same rules do not apply to outpatient services, or part B of Medicare. The Subcommittee found that if the Medicare program reimbursed all cataract surgery at the inpatient rate of $2400, regardless of surgical setting, a savings of at least $1.2 billion would be realized in 1985, and a total of almost $9 billion by 1990. Given current reimbursement practices, Medicare will waste $1.2 billion in 1985 alone.

Another factor fueling fraud, waste, and abuse in cataract surgery relates directly to the price of the IOL and Medicare reimbursement practices relating to the IOL. In 1984, the price of an IOL reimbursed by the Medicare program ranged from $322 to $750. The manufacturing cost for an IOL is roughly $35-$50. Under the DRG system many hospitals have gone to competitive bidding, reducing IOL prices by 50% or more, sometimes less than $100 a piece. Where outpatient surgery is performed, there is no corresponding pressure to reduce IOL prices as mentioned above because Medicare will pay what it terms "reasonable" cost ranging from about $300 to $750 or more. It is obvious that the profit margins are very high and that some manufacturers are trying to stave off true competitive bidding by taking $50-$150 or more out of their profits to "buy off" some physicians and gain a competitive edge.

The Subcommittee found that evidence of improper inducements, kickbacks, and other illegal marketing practices is flagrant and inescapable. Inducements ranged from outright payments of cash to physicians (in the form of $50 deposits in Cayman Islands accounts) for each lens purchased, to "free stock" in the manufacturer, "free lasers" and other IOL surgery equipment, "donations" of one lens for every one purchased, keys to resort condominiums, yachts, cars and houses, trips to Colorado, Europe, etc. for "medical" skiing seminars, and large payments for phony consultant work and to FDA "investigators". Large donations to the physician's favorite charity or personal research foundations by IOL representatives were also uncovered. Our investigation confirmed the judgment of one physician who told the Subcommittee, "The whole system is corrupt and is corrupting physicians, mostly I feel, out of ignorance — but of course greed is a big factor. Some very big names in ophthalmology are receiving large financial incentives to PR the companies' implants. I'm happy to see you investigating this and though it casts a shadow on my profession — if we can stop the 20% or so who are unethical it may restore people's faith in my profession."

Over one million IOLs, manufactured by about 20 companies in the United States, will be implanted in 1985, costing on the average almost $400 apiece. Medicare will pay for approximately 816,000 of these implants, totalling about $325 million. Out of those 20 companies, the Subcommittee found only several companies who were making a conscientious effort to avoid illegal practices. Evidence suggests that about half the price of each lens is lost to fraud and improper inducements resulting in a loss to the Medicare program in 1985 of about $160 million.

Finally, leading health and medical experts have reported that 23%-36% of all cataract surgery may be unnecessary or represent overutilization, and that second opinions should be sought by those considering such surgery. Many Americans may show signs of cataracts but have no functional inpairment. It is at this point in the decision

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- Called upon the General Accounting Office to conduct a review of Medicare reimbursement practices to determine regionally what Medicare pays for cataract surgery.

process that unnecessary surgery may occur. In some cases, this decision is simply a matter of poor judgment on the part of the physician. In other cases, however, the Subcommittee found instances where doctors in one southern state were inserting IOLs into the eyes of elderly patients with 20-20 vision. About $819 million will be lost to the Medicare program and cataract patients due to unnecessary surgery in 1985. Of this total, $525 million will be lost by the Medicare program alone.

Section I of this report provides the definition of cataracts and treatment methods for correcting this disabling disease. In addition, the costs and reimbursement mechanisms for this surgery are detailed, as are the numbers served and the industry which exists to meet this population's needs.

Cataracts will affect almost everyone who lives long enough. About 15 million persons over age 65 have some signs of cataracts today. Fortunately, the method for treating cataracts is unquestionably successful and frequently administered — over one million surgical procedures correcting the complications of cataracts will be performed in the U.S. in 1985 at a cost to the government and the taxpayer of $3.5 billion — making cataract procedures the most frequently performed major surgical procedure reimbursed by the Medicare program today.

Section II of this report discusses the problems surrounding cataract surgery which include waste, fraud, and abuse. The Subcommittee also found costs associated with the surgery and Medicare reimbursement practices are excessive — resulting in a loss to the government and taxpayer of about $2 billion annually; and that a number of regulatory and industry practices, if left unchecked, will continue to fuel widespread fraud, waste and abuse. In addition, the Subcommittee found that at least 23% of such surgery may be unnecessary.

Sections III and IV describe data collected from ophthalmologists and IOL manufacturers from which the Subcommittee was able to reach the following conclusions:

- The majority of ophthalmologists surveyed told the Subcommittee that they were aware of abusive practices in the marketing of IOLs.
- Inducements to use certain IOLs were common and included the purchase of second homes, cash payments, free equipment, stock in the company and free travel, among others.
- The majority of ophthalmologists told the Subcommitee that such offers are commonplace and should not be encouraged.
- Many manufacturers do not like the sales tactics the Subcommittee has found prevalent in the IOL industry.

Section V is a candid conversation between an ophthalmologist and an IOL salesman. It details an offer of free business equipment in exchange for doing business exclusively with a particular IOL manufacturer.

Section VI discusses Federal action with respect to cataract surgery in the United States, and Section VII includes a number of policy options for the consideration of the Congress and the consumer:

- The Health Care Financing Administration should take measures to control outpatient costs associated with cataract surgery;
- The Health Care Financing Administration should standardize payment for cataract surgery;
- The Food and Drug Administration should take immediate action to eliminate "adjunct" studies; and
- Seniors should seek second opinions before pursuing cataract surgery.

What this report concludes is that the Government and the taxpayer will continue to lose about 50 cents of every dollar they pay for cataract surgery unless corrective action is taken. What is not discussed but implicit in this report is the extent to which the health and welfare of every patient, who is usually elderly, will be forsaken as the result of current practices that remain unchecked.

INTRODUCTION

Cataract surgery. This is a common operation for persons over the age of 65 — for if one lives long enough, one will probably get a cataract and require such surgery. In the United States today, a person living a normal lifespan is more likely to undergo a cataract operation than any other major surgical procedure. Over 15 million older Americans, or roughly 60 percent, show signs of cataracts today. Of this number, over 1 million will seek cataract surgery (at a total cost of over $3.5 billion) in 1985 to correct this disabling and potentially blinding disorder. Fortunately, this operation is almost always dramatically successful.

The word cataract is derived from a latin word meaning "waterfall." In fact seeing through a cataract can be like trying to look through a waterfall. Cataracts are cloudy or opaque areas in part or all of the tranparent lens located inside the eye. They develop gradually and painlessly until, in some cases, light cannot pass through the lens and vision is seriously affected. Cataracts are the second leading cause of blindness in the United States today.

Treatment of cataracts involves the surgical removal of the cloudy lens and the replacement of the natural lens with either eyeglasses, contact lenses, or an intraocular lens (IOL) implant, all of which are referred to as "prosthestic" lenses. Each has advantages and disadvantages.

Eyeglasses have been used for decades to restore vision following cataract surgery and their value is unquestioned. However, they are extremely thick, heavy and limit peripheral vision. Compared with cataract eyeglasses, contact lenses provide a much more natural means of visual correction following surgery — peripheral vision is practically normal. The main disadvantages of contact lenses are that many elderly patients do not possess the manual dexterity necessary to handle them and the eye may not tolerate the contact lens or contact lens solutions. Intraocular lenses, or IOLs, developed in 1949, have the advantage of one-time insertion at the time of surgery, and require no attention from the patient in the future. Another advantage is the presence of immediately useful vision that continues at all times, under all conditions of work, weather, and general health.

IOLs have become the lens replacement of choice following cataract surgery. The percentage of cataract patients having IOLs implaced during surgery has increased from 35 % of operations in 1980 to the current level of about 85 %.

Today, in large part due to increased demand and inproved technologies, cataract surgery and IOL implantation have become big business. In 1985, the most frequently reimbursed major surgical procedure under the Medicare program was cataract surgery. The government, under the Medicare program, pays the lion's share of the $3.5 billion associated with cataract surgery, about 80 %. The rest comes out of the pockets of the seniors themselves.

What follows is a summary of the Subcommittee's investigation into cataract surgery in the United States. It is an attempt to determine whether Medicare's dollars are wisely spent, whether the taxpayer's dollars are wisely spent, and whether our nation's older Americans are receiving the most appropriate care available.

I. BACKGROUND

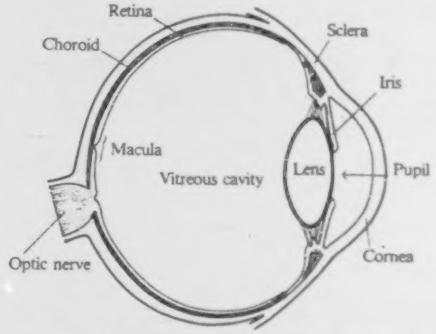
A. Cataracts: A Definition

If one lives long enough, one will probably get a cataract. Today, one million older Americans, or roughly about 60 percent of people between the ages of 65 and 74 show some signs of cataract, and about 3.3 million people in the United States are visually impaired by this disorder. At least 43,000 people are blind from cataracts, making it the second leading cause of legal blindess in the United States; about 4,700 new cases of blindness from cataracts occur each year. In sum, a person living a normal life span is more likely to undergo a cataract operation than any other major surgical procedure, and no other operation is as frequently dramatically successful.

The word cataract is derived from the Latin word "cataracta", which means waterfall. In fact, seeing through a cataract can be like trying to look through a waterfall.

Cataracts are cloudy or opaque areas in part or all of the transparent lens located inside the eye. Normally, the lens is clear and allows light to pass through. When a cataract forms, light cannot easily pass through the lens and this affects vision. See Figure I below.

Figure I



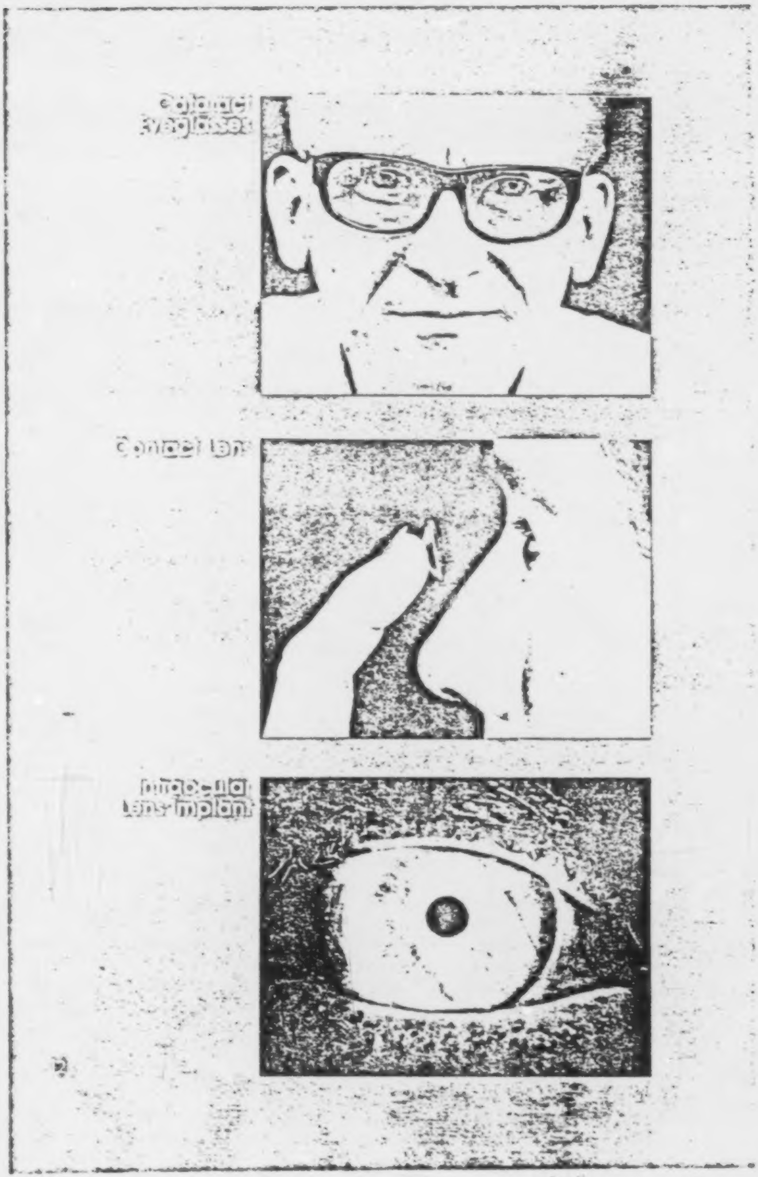
Cataracts usually develop gradually, without pain, redness, or tearing in the eye. Some remain small and do not seriously affect vision. If a cataract becomes larger or denser, however, it must be surgically removed to restore sight. Cataract surgery is a procedure in which the cloudy lens is removed. It is a safe procedure that is almost always successful.

What causes a cataract? When a cataract forms, there is a change in the chemical composition of the lens. It is not known what causes these changes. Cataracts have been associated with a number of different conditions, including aging, and eye injuries. What is not known, in most cases, is how and why these conditions cause the lens of the eye to cloud up.

What are the different kinds of cataracts? According to the National Eye Institute, the most common forms of cataract are as follows: senile cataracts are related to aging, although this type can occur at or before age 50. Congenital cataracts are present at birth or develop within a year after birth. Traumatic cataracts are those resulting from an eye injury or exposure to harmful chemicals. Drug-induced cataracts are those induced by the toxic effects of certain drugs that are given as medication, chiefly cortisone and its derivatives. Radiation cataracts are associated with radiation (such as X-rays and microwaves), intense heat or intense light (ultraviolet light or sunlight). Secondary cataracts are those that are complications of eye or general disorders. People who have glaucoma, iritis, uveitis, or ocular tumors may develop cataracts. Diabetes and other metabolic disorders can also lead to cataract formation.

Signs that cataracts are forming include hazy, fuzzy, or blurred vision; the appearance of dark spots in the field of vision; the need for frequent changes in eyeglass prescriptions; a feeling of having a film over the eyes; changes in the color of the pupil, which is usually black; and problems with light, for example, night driving. Of course, none of these signs separately or together necessarily means that a person has a cataract.

Figure II[1]


Cataract Eyeglasses
Contact Lens
Intraocular Lens Implant

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[1] Cataracts, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Washington, D.C., NIH Publication No. 83-201, September, 1983, page 12.

B. Treatment of Cataracts: Methods, Progress, and Developments

Treating cataracts involves two steps. The first is surgical removal of the clouded lens by an ophthalmologist. According to the National Eye Institute, this is the only method proven effective for treating cataracts. The second step is finding the appropriate substitute for this natural lens.

Basically, there are two surgical methods for removing the clouded lens: intracapsular and extracapsular extraction. These methods are described later in this report.

When the cloudy lens, or cataract, is surgically removed from an eye, the resultant state is termed "aphakia." The aphakic eye lacks the optical power to bring visual objects rays to focus on the retina, permitting those objects to be seen.

There are three options for replacing the natural lens removed in cataract surgery: eyeglasses, contact lenses, or an intraocular lens implant, all of which are otherwise referred to as "prosthetic lenses." (See Figure II on the following page.) Each has advantages and drawbacks.

1. Eyeglasses

Eyeglasses have been used for decades for the correction of aphakia, and their value is unquestioned. They provide sharp central visual acuity and still serve as the visual standard against which other methods of correction are judged. However, they do have certain disadvantages; they are heavy, thick, and magnify all objects viewed. Other unpleasant effects can include poor side vision, poor depth perception, headaches, dizziness, and nausea.

The effect of image magnification is perhaps the most disconcerting attribute of spectacle cataract correction, for it makes it impossible to wear a cataract glass for one eye and routine corrective lens over the other. This occurs because the magnification of the aphakic image in comparison to the image from the nonoperated eye are different sizes, producing intolerable blur and double vision. Many patients find this effect hard to understand before cataract operation, and thus are particularly surprised and unhappy to learn that they must use one eye or the other after the operation, but not both. Since many patients have advancing cataract in one eye with very few changes in the other, there may be years between operations on the two eyes, creating a long interval of visual disability. Such patients will probably be advised to use a contact lens, or to have a lens implant as part of the operation to remove the cataract.

Only a minority of cataract patients today are prescribed cataract eyeglasses following cataract surgery given the advantages of alternative prosthetic lenses.

2. Contact Lenses

Compared with spectacle lenses, contact lenses provide a much more natural means of visual rehabilitation following cataract surgery. Objects are still magnified — much less so — and peripheral vision is practically normal. Also, contact lenses are quite safe if handled and maintained properly, and are especially helpful after cataract extraction in one eye. The main disadvantages of contact lenses are that many elderly do not possess the steady hands necesseary to handle them and the eye may become allergic to the lens or to the contact lens solutions. Finally, one age-related change in the human eye is decreased production of one or more components of tears, and good tear production is essential for the use of contact lenses.

Recently, high water content contact lenses have become available, which can remain in the patient's eye for extended periods of time. These lenses are more convenient for elderly patients, but are associated with an increased incidence of corneal infections and thickening of the cornea. Often a family member must be instructed regarding the removal and care of the contact lens should an emergency arise in which the patient is unable to manage.

Wearing contact lenses requires periodic ophthalmic follow-up and most types of soft contact lenses must be replaced yearly. It is estimated that over a period of 20 years contact lenses are approximately three times as expensive as intraocular lenses for the correction of aphakia.

For near tasks, like sewing or reading, regular eyeglasses (not cataract spectacles) are required in addition to contact lens.

3. Intraocular Lenses (IOLs)

The third form of aphakic correction is the intraocular lens implant. This has the advantage of one-time insertion at the time of surgery, with no attention required from the patient in the future. Another advantage is the presence of immediately useful vision that continues at all times, under all conditions of work, weather, and general health.

These lenses are usually fabricated of rigid plastic, although the mechanical appendages that stabilize the lenses in the eye can be of other synthetic materials, such as Prolene or nylon. The general shape of these lenses, their location in the eye, the type of operation required for their insertion, and frequency of use will be discussed later in this report. Conventional eyeglasses (not cataract spectacles) often are required in addition to intraocular lens implants.

Because of the many advantages, lens implants have been used with increasing frequency in recent years. There has been a steady increase in the number of cataract operations, fueled, in part, by the increasing number of elderly. The percentage of cataract patients having IOLs implanted has increased sharply from 32% in 1980 to the current level of about 85%. This growth has accelerated in the last few years, probably as a result of the acceptance of IOLs and a growing patient awareness that it is no longer necessary to have the extremely thick, uncomfortable and limiting glasses which previously were prescribed for cataract patients. In addition, cataract removal has become a much simpler surgical procedure with new techniques and better surgical instruments, which will be discussed later in this report. A history of the development of intraocular lenses follows.

Historical Development of IOLs

Harold Ridley, a British ophthalmologist, carried out the first IOL implant operation on November 29, 1949. Observing that fragments of plexiglass from shattered cockpit canopies could be tolerated within the eyes of British airmen, he began the era of IOL implantation by designing a lens that could be inserted into the posterior chamber between the iris and remaining posterior capsule. (See Section IX on the anatomy of the eye) His first patient, a 45-year-old woman, had a severe residual myopia. She tolerated the lens relatively well. He was thus encouraged to perform his second implantation on the 23rd of August, 1950. Ridley inserted approximately 1,000 of his original IOLs. Many of his cases remained successful as late as 1966. By 1970, however, Ridley reported that removal of his implants was necessary in at least 15% of cases.

A major reason for Ridley's limited success was that the surgical techniques and instrumentation available in 1949 were not comparable to today's technology, not the least of which are the operating microscope and neodymium-YAG laser. For example, the operating microscope allows much greater access and visualization of the tiny, delicate portions of the eye.

The difficulties associated with Ridley's posterior chamber IOL led to experimentation with anterior chamber IOLs. In 1952, Baron was the first to implant an anterior chamber lens.

In June 1953, following the continued development of anterior chamber IOLs, Epstein introduced the "collarstud" lens, which was an iris supported lens. The original iris-clip lens was introduced by Binkhorst in 1957 and used for the first time in 1958. The iris-fixated lenses attempted to overcome complications of posterior chamber lenses, namely lens dislocation, and the most important complication arising from anterior chamber lenses, namely lens corneal touch and corneal damage.

Many of the iris-supported lenses were very successful and did much to popularize the concept of intraocular lens implantation throughout the world. Indeed, many patients who have had excellent long-term visual rehabilitaiton with IOLs of this type survive today. However, there are others who have experienced complications with these IOL styles. This has led to an eventual abandonment of these styles in favor of well-designed modern anterior and posterior chamber lenses. From February 1978 to August 1982, the rate of iris-fixated lenses implanted (expressed as a percentage of total IOLs implanted) declined from 52% to 6% of lenses implanted.

From 1975 to the present, information from the extensive clinical experience with IOLs during the past decades has contributed to a rapid and highly innovative era of IOL development. Of utmost importance has been the increasing use of posterior chamber implantation. Numerous modern, well-designed anterior and posterior chamber IOLs have been introduced. There has been continuous improvement in lens design and in IOL manufacturing techniques. Implantation techniques are far more refined and are safer.

In some instances, the frequent introduction of new IOL designs (Table I is only a partial listing of IOL models available to surgeons) actually creates a problem. It is sometimes difficult for the implant surgeon to decide which IOL is the best in his or her view and for each individual patient.

Although a few iris-supported lenses continue to be implanted, they have largely become obsolete. The overall rate of success achievable with these lenses cannot compare to the results obtained by experienced surgeons with modern posterior and anterior chamber IOLs.

The most important breakthrough was a return to Ridley's original idea of the posterior chamber IOL. This is now possible because of : 1) the development of new lens designs which are lighter in weight and provide better fixation, and 2) the introduction of improved surgical instrumentation and techniques. Table I, which follows, displays the evolution of intraocular lenses.

Table I

*Evolution of Intraocular Lenses**

Generation I — (ca 1949-54)† — Original Ridley Posterior Chamber Lens

1. Ridley, 1949
2. Parry (implantation modification, 1954)

Generation II — (ca 1952-1962) — Development of Anterior Chamber Lenses

1. Rigid or semi-rigid
   - Baron, 1952, 1954
   - Scharf, 1953
   - Strapelli tripod, 1953
   - Schreck, 1954
   - Bietti, 1955
   - Choyce Mark I, 1956
   - Ridley Mark I and II, 1957, 1960
   - Boberg-Ans, 1961
2. Flexible or semi-flexible loops
   - a. Closed loops
     - Dannheim, 1952
     - Strampelli, 1956
     - Lieb and Guerry, 1957
   - b. Open loops
     - Barraquer, J-loop, 1959

Generation III — (ca 1953-1970) — Continued Development of Anterior Chamber Lenses and Introduction of Iris-supported Lenses

Anterior Chamber

1. Rigid or semi-rigid
   - Choyce Mark II, 1957 to Choyce Mark VIII, 1963
2. Flexible

Iris-supported

- Epstein "collarstud" lens, 1953
- Binkhorst iris clip, 1957, 1958
- Epstein Maltese cross (evolved into the Copeland-Binkhorst lens), 1962
- Fyodorov Type I iris clip, 1964
- Binkhorst iridocapsular, 1965
- Fyodorov V-type II, Sputnik iris clip, 1968
- Worst Medallion iridocapsular, early 1970s
- Worst Platina, early 1970s

Generation IV‡ — (ca 1975 to present) — Major Improvements in Microsurgical Techniques, Lens Design and Lens Materials; Introduction of Posterior Chamber Lenses*

Anterior Chamber Lenses

1. Rigid or semi-rigid
   - Azar Mark II, 1977
   - Tennant Anchor, 1979
2. Flexible or semi-flexible loops or footplates
   - a. Closed loops
     - Leiske, 1978
     - Hessburg, 1981
     - Optiflex, 1981
     - Azar 91Z, 1982
     - Stableflex, 1983
   - b. Open loops or footplates
     - Kelman II, 3-point fixation, 1978
     - Kelman Quadriflex, 1981
     - Kelman Omnifit, 1981
     - Kelman Multiflex, 1982
   - c. Radial loops
     - Copeland, 1982

Posterior Chamber Lenses

- Pearce rigid tripod, 1975
- Shearing J-loops mid to late 1970s, early 1980s

Table I (cont.)

  - Simcoe C-loop, mid to late 1970s, early 1980s
  - Sinskey, modified J-loop, mid to late 1970s, early 1980s
  - Kratz, modified J-loop, mid to late 1970s, early 1980s
  - Clayman, modified J-loop, mid to late 1970s, early 1980s
  - Lindstrom, modified J-loop, mid to late 1970s, early 1980s
  - Harris, 1 open, 1 closed loop, modified J-loop
  - Closed modified J-loop both loops closed (e.g., Sheets, Galand, Knolle)
  - Osher-Fenzl, modified J loop with loophole at tip of superior loop
  - Lewicky, modified J-loop with loopholes at tips of both loops
  - Ridged lenses for YAG laser capsulotomy, e.g., Hoffer ridge
  - IOLs with UVR absorbers in optics
  - IOLs with biconvex or aspherical optics
  - Lynell, glass optic
  - Mazzocco silicone (elastic) IOL
- "Universal" types (designed to be placed in either anterior or posterior chamber" (early 1980s)
  - Shepard Universal (radial loops)
  - Feaster Dualens
  - Pannu type III

*Partial listing of representative lenses

†Some dates are estimates since manufacturers' data are not always available. We have attempted to document the date of the surgeon's initial implantation rather than the date of his published reports or year of marketing of the lens.

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2. "Complications of Intraocular Lenses. A Historical and Histopathological Review," Survey of Ophthalmology, Volume 29, Number 1, July-August, 1984.

C. IOL Implantation Procedure

Implantation of the intraocular lens (IOL) follows the removal of the patient's clouded lens (cataract) by the ophthalmologist. The procedure may be performed on an inpatient or outpatient basis, and local or general anesthesia can be used. The procedure can take anywhere from 20 minutes to two hours to perform, depending on methods used and operating conditions. Routine cataract extractions should take no more than 40 minutes and some physicians can perform this operation in 12 to 20 minutes. For the patient, the procedure can mean three hours in an outpatient facility or up to three days in the hospital.

Two different surgical procedures are commonly used for removal of cataracts and insertion of IOLs: extracapsular and intracapsular extraction. The extracapsular procedure has increased in use since 1981, displacing intracapsular extraction as the more common procedure. (See Table II below) According to Table II, between 1981 and 1983, extracapsular extraction increased from 29.4% to 51.9% of all surgical cataract procedures, while intracapsular extraction fell from 68.1% to 43.8%.

Table II

Shift in Type of Surgical Procedure
Used to Extract Cataract

	Extracapsular Procedure	Intracapsular Procedure	Other Procedures
1981*	29.4%	68.1%	2.5%
1982	39.3%	57.0%	3.7%
1983	51.9%	43.8%	4.3%

*1981 MEDPAR data indicate that 22.8 percent of cataract extractions were extracapsular and 78.2 percent of extractions were intracapsular.

Source: Hospital Discharge Survey, National Center for Health Statistics, for cataract extractions in patients 65 and over.

The extracapsular procedure tends to take longer, but both procedures including lens implantation should still require less than an hour of operating time Both procedures begin with a 5 to 7mm incision in the eye. Frequently, sodium hyaluronate (Healon), or a similar viscoelastic material, is used to maintain the shape of the eye and protect the cornea and other delicate structures during surgery.

Intracapsular extraction is commonly used to remove cataracts associated with aging, and is rarely used in patients under 30 years of age. In this method the entire lens and its capsule are removed. One popular technique uses an enzyme, alpha chymotrypsin, to weaken the ligaments which hold the lens in place. Then a very cold probe is inserted and used to freeze a portion of the lens. The frozen part of the lens sticks to the probe and allows the surgeon to lift the lens out of the eye easily. This technique is called cryoextraction.

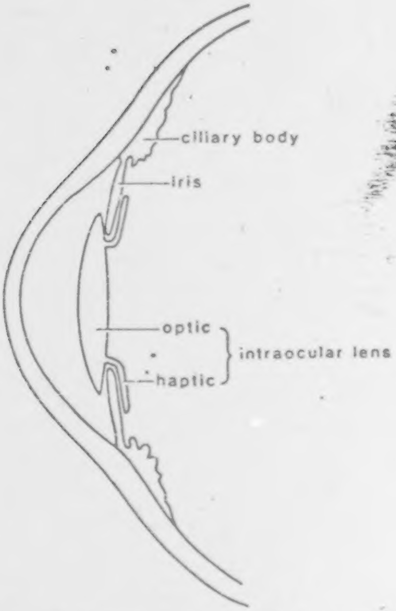
Extracapsular extraction leaves the back portion of the lens capsule intact, while most of the lens and the front part of the capsule are removed. The aspiration method is used to remove congenital and other cataracts in infants and young children, whose lenses are relatively soft. The lens capsule is opened and the soft lens is suctioned out (aspirated) through a hollow needle. For adult patients with harder lenses, the surgeon may employ phacoemulsification, a technique whereby high frequency sound vibrations are used to soften and liquify the lens, enabling the lens to be aspirated through the hollow needle.

After the lens is removed, one of three different types of IOLs can be implanted: the iris supported lens, the anterior chamber lens, and the posterior chamber lens. Iris supported lenses (see Figure III on the following page), anchored by loops to the iris, were the first to be used extensively. These lenses may move about when the eye moves causing corneal damage. Few iris supported lenses are implanted today.

Anterior chamber lenses (see Figure IV), placed in the angle between the iris and cornea, must be accurately sized. They are easy to install and remove, making them very popular.

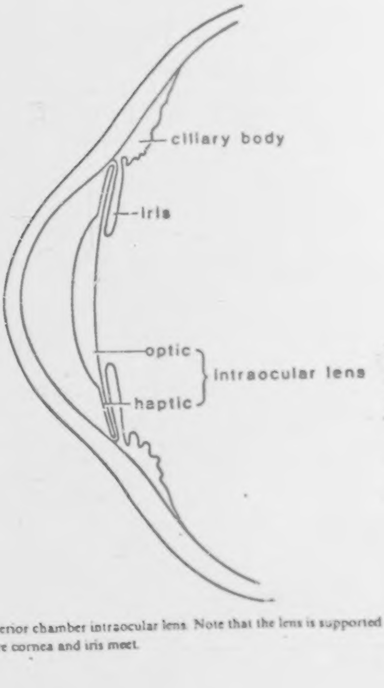
Recently, the combination of an extracapsular cataract extraction with the implantation of a third type of lens, the posterior chamber lens (See Figure V) has become the most popular procedure in the United States. Extracapsular extraction is advantageous for two reasons. First, the remaining portion of the capsule tends to hold the vitreous humor, a viscous fluid found in the eye, in its normal anatomical position in the back of the eye. Second, the capsule itself serves as a support for the posterior chamber IOL, which in this case rests behind the pupil in the natural position of the patient's own lens.

Figure III


ciliary body
iris
optic
haptic
intraocular lens

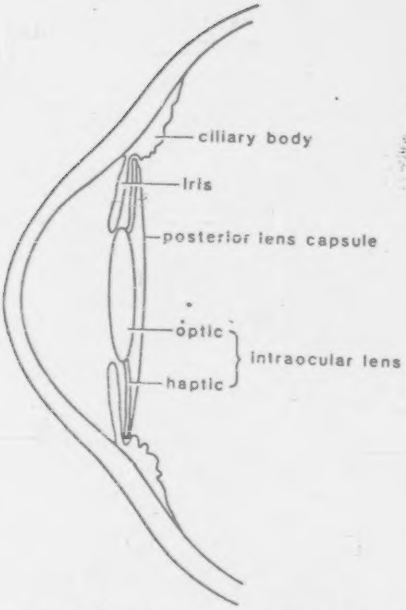
Iris-supported lens. This lens depends solely on the constricted iris for its support in the eye. In some cases, a suture is passed through a hole in the superior part of the optic securing the lens to the iris. This in turn allows partial diagnostic dilation without lens dislocation.

Figure IV


ciliary body
iris
optic
haptic
intraocular lens

Anterior chamber intraocular lens. Note that the lens is supported by the tissue in the angle where cornea and iris meet.

Figure V



Posterior chamber intraocular lens. This implant rests primarily on the posterior lens capsule left behind when the extracapsular cataract extraction is performed.

With the extracapsular extraction-posterior chamber IOL there is a tendency for the capsule to become somewhat opacified several months after the operation. This complication, occurring in 40-50% of patients, necessitates an incision of the capsular membrane with a surgical knife or a non-heat producing Nd:YAG (neodymium-yitrium garnet) laser. The laser treatment is essentially non-invasive and atraumatic for the remainder of the structures in the patient's eye.

Even with the possibility of subsequent membrane formation (clouding), many ophthalmic surgeons are convinced that the posterior chamber lens implant is superior to those described above and it seems likely that the majority of lens implantations done in the United States over the next several years will be of this type. While only 4% of IOLs implanted in 1978 were posterior chamber lenses, today about 60% of implantations involve the use of these lens. (See Table III below).

Table III

Percent of Intraocular Lenses Implanted By Type of Lens For Each Six Month Period

	1978	1979		1980		1981		1982		1983		1984
Type Of Lens	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb	Aug	Feb
Anterior Chamber . . .	25%	25%	32%	31%	32%	32%	35%	37%	41%	36%	32%	30%
Posterior Chamber . .	4%	8%	13%	21%	30%	37%	43%	47%	50%	58%	65%	69%
Iridocapsular	19%	17%	13%	10%	8%	7%	4%	3%	2%	1%	< 1%	< 1%
Iris Fixation	52%	50%	42%	38%	30%	24%	18%	13%	7%	5%	2%	< 1%

Source: Stark, Walter, et al. [illegible] of Intraocular Lenses Implanted in the United States. Ophthalmology, [illegible] 1984

D. IOL Industry: U.S. and Abroad

The manufacturing and distribution of IOLs is a fast growing, highly competitive and highly profitable industry in this country. In 1985, the IOL industry will sell $325 million worth of its lenses. Most were implanted in the eyes of elderly patients following cataract surgery. Fueled by the increasing number of elderly, the growing acceptance of IOL implants, and unbridled Medicare payments for IOLs, estimates are that IOL sales will hit $700 million by 1990 when well over one million IOL implants will be performed in the U.S. each year.

The percentage of cataract patients having IOLs implanted has increased sharply, from 32% in 1980 to the current level of 85%. This has resulted in rapid growth for the entire industry. Today no fewer than 30 companies worldwide are in the business of making IOLs, putting out at least 400 different models. The field is dominated by five large medical companies which entered the market by acquiring much smaller firms in the late 1970s, and together they control over 70% of the market. The leaders, by sales volume, are Johnson & Johnson's IOLAB, Rorer Group's CILCO, Intermedics, Optical Radiation Corporation, American Medical Supply's American Medical Optics, and Frigitronics' Precision Cosmet. (See Table IV)

Table IV — Major IOL Manufacturers

Allergan/ISP, 2525 Dupont Drive, Irvine, California 92713.
American Medical Optics, 1402 East Alton Avenue, Irvine, California 92714.
Americal IOL International, 15542 Graham Street, Huntington Beach, California 92647.
CILCO, Inc., 1616 13th Avenue, Huntington, West Virginia 25701.
Coburn Optical, 1375 South Ft. Harrison, Clearwater, Florida 33517.
CooperVision, Inc., IOL Division, 3190 160th S.E., Bellevue, Washington 98008.
Copeland Intra Lenses, Inc., 129 East 61st Street, New York, New York 10021.
Eye Care Corporation, Suite 100, 201 Summit View Drive, Brentwood, Tennessee 37027
Intermedics Intraocular, Inc., 169 North Halstead Avenue, Pasadena, California 91107
IOLAB Corporation, 861 South Village Oaks Drive, Covina, California 91724.
Ioptex Inc., 1301 Optical Drive, Azusa, California 91702.
Optical Radiation Corporation, 1300 Optical Drive, Azusa, California 91702.
Pharmacia Ophthalmics, 800 Centennial Avenue, Piscataway, New Jersey 08854.
Precision Cosmet, 11140 Bren Road West, Minnetonka, Minnesota 55416.
Surgidev Corporation, 5775 Wayzato Boulevard #855, Minneapolis, Minnesota 55146.
Staar Surgical, 1911 Walker Avenue, Monrovia, California 91016.
Storz Instrument Company, 3365 Tree Court Industrial Boulevard St. Louis, Missouri 63122.
3M Vision Care IOL, 340 Storke Road, P.O. Box 2360, Goleta, California 93118-2360.

Positions can shift quickly in this immensely profitable and competitive industry due to innovation and marketing. The unique way in which the FDA regulates this market facilitates market entry and expands the ranks of competitors. This will be discussed in greater detail later in this report. For example, Optical Radiation entered the market four years ago with the first IOL with a UV light blocking additive, and now owns at least 13% of the market. For its part, the FDA has been slow to grant full approval to market IOLs, while it allows distribution to qualified surgeons on an almost unlimited basis prior to approval. In order to use the lens the surgeon is required to complete paperwork which makes him part of the investigative process. There are now over 900 IOL models being marketed, but only 76 have received full FDA approval. The first approval came in 1981, by which time there were over 500,000 lenses implanted.

To stay ahead of their competitors, the major companies spend on average 10% of their revenues for research and development of new lenses. They spend enormous sums of their money on marketing and have even engaged in price cutting to gain additional market share.

Comparing the industry in the U.S. and abroad, the main difference seen is in the costs to consumers for lenses. The costs in Europe are roughly half of what they are in the U.S. while the cost to the manufacturer per lens ($35-$50) is roughly the same.

The outlook for the industry in the U.S. is positive for the next few years as the population ages and the increase in the number of cataract operations continues. It is suspected however that the recent sharp increase in cataract operations are using up a pool of those who were postponing the operation as long as possible, but went ahead when they were satisfied with the success of IOLs. The total number of operations should level off sometime in the mid-1990s, when the capacity to perform these operations catches up with the population requiring them.

E. Cataract Surgery: Numbers and Costs

Cataract surgery is a large and ever growing industry in this nation. This year Americans will spend over $3.5 billion for the removal of over 1.1 million cataracts and the implantation of over 1 million IOLs. The rate of cataract surgery has more than doubled since 1980 and it is projected to double again by the end of this decade. In 1980, there were 415,000 cataract operations. In 1989, over 2 million such surgeries are expected to be performed. (See Table V)

Table V

U.S. Cataract Procedures
(1984-1989)

	1984(a)	1985(b)	1986(b)	1987(b)	1988(b)	1989(b)
Total Cataract Procedures	989,207	1,187,000	1,424,000	1,709,000	2,051,000	2,200,000
IOL Implants(c)	840,650	1,020,820	1,238,880	1,486,830	1,784,370	1,914,000

(a) 1984 figures based on actual FDA data.
(b) Projected.
(c) Included in Total Cataract Procedures above.

Other relevant facts relating to cataract surgery include:

- $3.03 billion was paid by the Medicare program alone — the rest came out of seniors themselves.
- Most cataract patients and IOL recipients are elderly. Roughly 900,000 of the over one million IOL implantations to be performed this year will involve older Americans.
- Since the late 1970s, IOL sales have increased from virtually nothing to well over $300 million. Those knowledgeable in the IOL industry estimate that the actual cost of manufacturing a standard quality IOL should range from $35-$50.
- The price of an IOL through competitive bidding in the hospital is sometimes less than $100 in 1985. The price of an IOL to the Medicare program out of hospital is $300 to $750 in 1985.
- The Subcommittee indicates the final cost to the purchaser of cataract surgery (whether that is the Medicare program or private consumers or some combination thereof) ranges from around $300 to $750 and over.

F. Medicare Payment for Cataract Surgery and IOLs

The lion's share of monies paid for cataract surgery come from the pockets of the American taxpayer. The Federal government through the Medicare program pays upwards of 85 percent of this nation's annual bill for cataract surgery ($3.03 billion out of a total of $3.56 billion this year).

The Medicare program, which is authorized under title XVIII of the Social Security Act, consists of two separate but complementary types of health insurance for the aged and certain disabled persons. Part A, the hospital insurance program, provides protection against hospital and related institutional costs. Part B, the supplementary medical insurance program, covers physicians' services and a number of other medical services.

Under Part A, the Health Care Financing Administration reimburses hospitals for inpatient care on a prospective basis, subject to specified deductible and coinsurance amounts. All inpatient treatments and surgical procedures have been classified and assigned to one of 467 different diagnostic related groupings (DRGs). This approach to health care reimbursement operates on the principle that patients with similar medical conditions should receive similar care and should use approximately the same amount of resources; therefore, in general, a hospital should be reimbursed the same amount for each patient in a DRG. The inpatient deductible in 1985 is $400.

Part A generally does not cover physician services rendered to hospital inpatients; payment for such services is made under part B. Part B pays 80% of a patient's doctor bills and 80% of bills for outpatient services, after the patient exceeds his or her one-year deductible. The patient deductible in 1985 is $75.

For cataract surgery and IOL implants, serious concerns have arisen over the very different amounts of reimbursements and beneficiary contributions which Medicare creates — depending on where and how the identical surgery and procedures are performed, be it in the hospital as an inpatient or outpatient, in an ambulatory surgical center (ASC) or freestanding surgical clinic, or in a physician's office. The surgeon performing the operation receives from Medicare roughly the same fee of $1200 regardless of where the cataract surgery is performed. The discrepancies arise when one looks at the costs for facility fees and lenses at the different locations, which will be discussed in detail in Section II B of this report.

II. CURRENT PROBLEMS

A. Efficacy and Safety

Recent improvements in IOL design, manufacturing,and surgical techniques have greatly reduced the incidence of complications following implantation, and many authors now consider IOL implantation one of the most safe and effective major surgical procedures. However, adverse reactions are still seen — some as late complications of earlier IOL designs and implantation techniques, and some as the result of more recent implantations using "state of the art" lenses and surgical techniques. Complications may be due to various factors including surgical technique, IOL design, or the inability of some eyes with preexisting diseases to tolerate an implant.

Ophthalmic surgeons generally feel that 95% of cataract patients achieve what might be termed "technical success." This refers to a lack of significant complications related to the removal of the opaque lens, but does not allow for underlying, unexpected abnormalities of the retina or optic nerve, which can seriously interfere with final visual capability. When intraocular lens implants are used, additional complications can occur as a result of the lens implant itself. For example, the basic cataract operation is made somewhat more difficult technically by implant placement, so that there is a slightly greater likelihood of damage to the cornea, iris, or vitreous body. More important are those complications, such as lens dislocations and chronic inflammation, that are specifically due to the plastic implant. These complications may occur in an additional 2 to 3% of cataract patients, and of course are added to those complications of the usual cataract operation. Most patients are willing to commit themselves to this slightly higher risk of complications to achieve the benefits of the intraocular lens implant.

As part of the healing process which occurs following removal of a cataract and insertion of an intraocular lens, portions of the implant which are in direct contact with soft tissues inside the eye usually become imbedded within those tissues. In the vast majority of cases implants are well tolerated and this "healing-in" process actually stabilizes the implant. On rare occasions, however, the implant may cause a low-grade, chronic inflammation within the eye. Many surgeons now feel that if the supporting elements of the posterior chamber lens are inserted within the relatively inert capsular bag, this potential problem can be avoided altogether.

In the past, insertion of poorly manufactured intraocular lenses produced inflammatory reactions, intraocular bleeding, and reduced visual acuity. Strict quality control measures during the past few years have largely eliminated these problems.

Only rarely does an IOL implant require subsequent removal. The usual indication for this is persistent inflammation. Persistent glaucoma, or advancing corneal degeneration as a result of the implant may also be indications for lens removal. Persistent inflammation may be coupled with persistent swelling of the macula of the retina (cystoid macular edema), may lead to a significant reduction in visual acuity. Whether or not the removal of the implant is useful in reversing this complication is not entirely clear, but most surgeons feel that it is prudent to remove the implant if the retinal edema persists for more than a few months.

One IOL which deserves special mention is the ultra violet (UV) lens, an IOL with an additive which filters out UV light before the light reaches the retina. Many surgeons say they buy UV lenses because their patients ask for them, not because they believe in them. Despite the publicity and claims made for UV lenses, there is no medical evidence that ultraviolet light damages the retina. There is also no information on the long-term effects of the UV filtering additive used in these lenses. Ultraviolet light can also be blocked by glasses and, until further data is in, some experts believe glasses may be preferable to the UV IOLs.

Because current types of IOLs have been in use for little more than a decade, there has not been time to learn how these devices might affect the eye over a period of many years. However, results to date have been very encouraging. In the three decades since the introduction of IOLs by Ridley, successful tolerance has been measured over postoperative periods of 5-10 years. However, by today's implantation criteria, in which lenses are being implanted in younger and younger patients (who, by actuarial statistics, are going to be living longer and longer), IOLs should now be expected to be safe and stable within the eye for periods of 10-50 years. Therefore we have now reached an era where one of the most important considerations in IOL implantation is the need for very careful long-term follow up of patients. This is necessary for the surgeon to attain highly successful visual rehabilitation over the long term. To obtain additional information that will aid cataract patients and their doctors in making decisions about about the use of IOLs, the National Eye Institute is supporting research on these devices and their long-term safety.

B. Cost: IOLs and Medicare Reimbursement Practices

Medicare payments for cataract surgery with IOL implantation are made under a system which pays grossly different sums for identical surgical procedures, depending on where those procedures are performed. This system, designed to improve efficiency and save money, is doing just the opposite, and without regard to patient well-being.

The following elements are incorporated into the total IOL implantation cost borne by the Medicare program and, ultimately, the American taxpayer:

- manufacturing and marketing costs for IOLs;
- packs (disposable liquids, knives, tools, etc.);
- viscoelastic materials and operation-associated equipment;
- hospital or facility markup;
- hospitalization (inpatients only);
- operating room and related costs;
- professional fees, including the referring physician, surgeon (and assistant surgeon in some cases), and anesthesiologist (if used); and
- followup.

When the IOL implantation is performed in the hospital on an inpatient basis, the the hospital is reimbursed by the prospective payment system of Medicare part A, under DRG 39. When the same procedure is moved to the outpatient setting in the same hospital, outside of the DRG domain, that same hospital can now bill Medicare, under part B, its "reasonable costs" almost four times as much as Medicare's inpatient cost, for for the identical procedure bundled with fewer services.

Our investigation indicates costs are excessive and profits inordinate at two major levels: the price of the lens in hospital outpatient settings, and the facility fees paid to hospitals for outpatient cataract surgery and the lens implants. The cost of cataract surgery and lens implantation vaires greatly on the basis of where the implantation takes place: in the hospital, hospital outpatient, ambulatory surgical center, or in the physicians' office. With regard to these cost elements, our findings are as follows:

1. IOL Costs

The manufacturer's IOL list price includes the cost of materials and manufacturing processes, general administration, marketing and sales, research and development, tax and profit.

The average IOL currently costs \$35-\$50 to manufacture and is sold to hospitals and surgical centers in the United States for an average of \$322. (See Table VI). In practice, the principal difference between product cost and sales price consists of marketing and profit.

Table VI

Average Price of Intraocular Lenses And Healon

Lens Type	1981	1982	1983	1984
Posterior Chamber	$271.04	$280.04	$291.14	$314.60
Anterior Chamber	—	$290.69	$317.35	$336.39
IRIS Fixation	—	$267.94	$312.14	$308.31
Other	$268.59	$334.41	$456.81	$340.43
Healon	$ 53.35	$ 68.89	$ 62.59	$ 59.11
Weighted Average For IOLs	$268.77	$286.33	$305.17	$322.06
Weighted Average For IOLs And Healon	$283.43	$309.55	$345.85	$378.83

Source: IMS America, Ltd., 1985 Hospital Supply Index

Given the essential equivalency of the lenses and Medicare's insensitivity to price, it is not surprising that marketing costs are significant. Almost 50 percent of the list price of an IOL is dedicated to marketing. Roughly two thirds of that total — 30 percent of the list price — was paid by some firms as a commission to its sales representatives. The remainder was divided between direct marketing, advertising, travel, clinical investigations, and more innovative sales inducements. Some companies bundle $75 surgical packs with their lenses, and others even offer $85,000 YAG lasers with volume purchases.

Although the percentages may vary, and specific arrangements with the firms sales representatives differ, the general pattern is consistent. IOLs tend to be immensely profitable to manufacture and market.

IOLs are more profitable in the U.S. than abroad. A recent report in Barron's asserts that the very same lenses that are sold in the U.S. for $300 are sold in Europe for $120 to $150. To defend this pricing difference, one manufacturer told us that 99% of IOLs in the United States are supplied to hospitals on a consignment basis, resulting in additional inventory and handling costs of up to $50 per lens. In addition, we were told, the FDA requires paperwork amounting to an additional $30 per lens. Thus the manufacturer accounted for roughly half the pricing difference. A securities firm which follows the IOL industry asserted that in Europe, the bulk of lens sales are comprised of generic (standard) lenses, while the product mix in the U.S. is weighted more heavily in favor of the more expensive, technologically advanced, though questionably superior, products. While the eyes and sight of the citizens of Europe are no less precious than those of our own citizens, their governments have refused to pay exorbitant amounts for premium IOLs, when their national health insurance can provide perfectly adequate quality lenses for much less money. This is something Medicare is supposed to do.

Further evidence of the profitability of IOLs is shown by the willingness of manufacturers to reduce prices when hospitals required them to make competitive bids in order to secure lens purchases. As shown in Table VII on the following page, one hospital was able to reduce its average cost per lens from $321 to $229 just by requiring manufacturers to submit bids. One manufacturer actually reduced its IOL price by 58 percent. On volume purchases, some models of lenses may be acquired for less than $100.

In all, the Subcommittee found IOLs offered for sale to providers from $90 to $385. Discounts were offered by most manufacturers, some only when asked. Requiring competitive bids, and making volume purchases, are the most assured ways for hospitals, surgical centers, and consortiums to get the best possible prices for IOLs.

Hospitals performing inpatient IOL implants have a direct incentive to keep their costs for IOLs down — they receive a flat fee of $1,200 for facility expenses, including the lens, under DRG 39. Any extra dollar they spend for an IOL eats into their already tight margins and could even put them into the red. For hospitals performing inpatient surgery, it is clearly in their own best interest to buy IOLs at competitive prices.

Unfortunately, Medicare Part B, which covers IOLs implanted in outpatient settings, provides no incentives for keeping IOL costs down. In fact, it does just the opposite, encouraging outpatient facilities and Ambulatory Surgical Centers to pay top dollar for their IOLs, and then pass the cost on to Medicare. Some hospitals even mark up the IOL by as much as 280 percent, as can be seen in Figure VI on the following page, detailing patient charges at a Colorado hospital.

At present, many hospitals and ASCs are charging Medicare what they feel are "reasonable" costs for IOLs. They are paying the lens manufacturers their full "reasonable" list prices and then, after adding a "reasonable" markup for themselves, pass the entire "reasonable" cost on to Medicare. Medicare B encourages this practice by reimbursing providers for IOLs on a reasonable charge basis.

The reasonable charge is defined as the lowest of:

- the actual charge;
- the customary charge for the IOL (that is, an amount high enough to cover the IOL charges 50 percent of the times the IOL was purchased; or
- the prevailing charge for the area (that is, an amount high enough to cover 75 percent of the customary charges of all IOLs implanted in the area).

Table VII

	Before Bids				After Bids					
VENDOR	% of Business	Average Cost Per Lens	Number of Lens	1983 Annual Cost	% of Business	Discount	Average Cost Per Lens	Number of Lens	Projected Annual Cost	Project Annual Savings
Company A	9.8%	$350	147	$ 51,260	3%	15%	$298	64	$ 19,072	$ 3,328
Company B	3.5%	$325	52	$ 16,900	13%	58%	$138	264	$ 36,432	$ 49,368
Company C	27.5%	$325	412	$133,900	21%	20%	$260	428	$111,280	$ 27,820
Company D	31.7%	$300	474	$143,675	12%	25%	$225	240	$ 54,000	$ 18,000
Company E	26.7%	$325	399	$129,675	48%	30%	$228	976	$222,528	$ 94,672
Company F	0.8%	$360	12	$ 4,320	3%	0	$360	68	$ 24,480	0
TOTALS	100%		1,496	$479,730	100%			2,040	$467,792	$193,188
COST PER LENS				$ 321					$ 229	

BASED ON USE OF 1,496 LENSES
IN CALENDAR YEAR 1983

BASED ON ANNUALIZED USE OF
2,040 LENSES IN FISCAL YEAR
1984-85

Figure VI

MEDICAL CENTER

PATIENT CHARGES

		Hospital Cost	Markup
Amoils cryo unit	$ 13.89		
Beaver blade #69	9.20		
Beaver blade #64, #67	3.45		
Concept cautery	13.25		
Drape, 1010	6.10		
Drape, 1060	14.66		
Drape, 1020	6.58		
Elbow pads	6.90		
Filters	4.90		
Instrument wipe	4.80		
Lens, Ioptex 304-01	661.20	. . . . . 290.00	228%
Lens, IopteX UV 304-1	798.00	. . . . : 350.00	228%
Lens, ORC UV	763.80	. . . . . 369.00	207%
Lens, Cilco Multiflex	946.20	. . . . . 335.00	282%
Lens, Cilco SK 21	741.00	. . . . . 340.00	218%
Lens, Iolab Sinskey 103N	741.00	. . . . . 325.00	228%
Lens, Coburn Mod 99	798.00	. . . . . unavailable	
Microknife	10.42		
Microscope	12.99		
Phacoemulsifier	425.86		
Phaco I & A	233.43		
Patch, eye	.69		
Shield, eye	3.45		
Suture, 4-0 Silk	8.00		
Suture, 9-0, 10-0	33.04		
Suture, allother	21.52		
Ultrasharp blade	41.04		
Weck-cel sponges	5.50		
Wet-field Cautery	13.25		
Vitrectomy Unit	328.60		

DRUGS

Adrenalin	4.50
BSS 15 ml	10.67
Carbocaine 20cc	4.78
Healon	137.50
Marcaine .75%	4.85
Maxitrol Oint	10.34
Miocohol	29.97
Tetracaine	2.31
Wydase	8.10
BSS pl	47.00
Zolyse	30.55
BSS ++	129.50

Rather than standardizing what Medicare pays for IOLs, this system allows IOL costs to vary widely from state to state, as can be seen in Table VIII below, which was gathered by the Subcommittee staff and the General Accounting Office in telephone interviews and written correspondence.

Table VIII

STATE	RATE(year)	RATE METHOD	Comments
Illinois	$375 ('83)	lesser of ivoice or $375 for all	invoices not required; with claims; few submit with claims
Michigan	$450 or $600('85)	set prevailing rates/ pay lesser of customary or prevailing	2 geo areas w/
New York	$295-$360('85)	4 set rates for 4 lense types based on 75th percentile of previous year charges	asked to submit invoice/ few do
Mass	$665('85)	pay lesser of $665 or invoice	invoices not required; few submit
Arizona	$400('85)	pay lesser of $400 or invoice	
Wisconsin	$290('84)	$240 flat	
California	$350('85)		

One lens manufacturer contracted with the largest accounting firm in the health care industry, to determine the shipping and handling costs for IOLs on a per lens basis. That study came up with a figure of $55.15 per lens, much less than the 50 to almost 300% markups many providers have been passing on to Medicare for IOLs.

If the Medicare payment system for IOLs were revised to encourage providers to shop around for the best lens prices available, and then to reimburse the provider for that sum plus a genuinely reasonable handling charge, savings from 50-75 percent of the price of each lens could be realized. This translates in to annual savings of over $160 million.

When compared to the total amount of federal dollars wasted paying excessive fees for IOL implantation, the total made in overpayments for the IOLs themselves becomes trivial. The current Medicare payment system has encouraged abusive practices, and as shall be shown, is responsible for more than $1.2 billion per year in overpayments for outpatient cataract surgery. (See Table IX on the following page.)

2. Inpatient Hospital

Under the prospective payment plan of Medicare part A, cataract surgery has been assigned to DRG 39. Another classification, DRG 42, is used in a minority of cases. Under DRG 39, hospitals receive from Medicare roughly $1200 (plus or minus $300 for regional differences) for facility fees incurred during cataract surgery. The hospital receives the same fee whether an IOL is implanted or not.

According to hospital industry sources, when the DRG was first adopted many hospitals lost money doing IOL implants. Since the introduction of the DRG system, hospitals have taken steps to reduce their costs. Hospitals have reduced the average length of stay for this procedure from 3.2 days in 1981 to 2.2 days in 1984, and many hospitals are shooting for a one-day stay. Hospitals are also saving money by putting

Table IX

The Cost of Cataract Surgery

	Medicare Costs by Location				
Location	Facility Reimbursement	IOL Reimbursement	Physician Reimbursement	Patient Charges	Total Cost*
Hospital Impatient	$1200 (reimbursement set by DRG 39)	-0- (included in facility reimbursement)	$1200-$1500	$400 Part A Deductible $315 Part B $715	$3115 to $3415
Hospital Outpatient	$1300-$3800	$300-$900	$1200-$1500	$560-$1180 Part B	$3360 to $7380
Ambulatory Surgical Center (ASC)	$ 553 Maximum	$300-$900	$1200-$1500	$60-$180 20% of IOL	$2113 to $3133
Physician's Office	-0- (no facility reimbursement)	$300-$900	$1200-$1500	$375-$495 Part B	$1875 to $2895

Total Cost does not include possible fees for assistant surgeons and anesthesiologists which may add over $500 to the bill. Such fees would usually be split between Medicare and the beneficiary, with Medicare paying 80%.

their quantity lens purchases out for bid. Many hospitals have also standardized their supplies and reduced staffing costs. As a result many of the same hospitals are now breaking even or showing a modest profit from cataract surgery.

The prospective payment system is, for the most part, having its intended effect on the costs of inpatient cataract surgery. Hospital efficiency has been improved and costs contained. In theory this should save money and be advantageous for many patients. In practice, most cataract surgery is being moved to an outpatient setting (due primarily to recently imposed government policies), outside the realm of the DRG system, where costs are not controlled and great profits can be made, as is discussed in the following section.

3. Outpatient Hospital

When cataract surgery with lens implantation is performed on a hospital outpatient basis, the facility is reimbursed by Medicare part B on a cost basis at 80% of reasonable cost. There is no ceiling on what is considered reasonable. In addition the outpatient center passes on to Medicare the cost of the IOL, an item which is included in the DRG payment for the inpatient procedure. A recent look at actual invoices for hospital outpatients' facility charges from around the country ranged from $1684 to $4570. No figures are available to obtain averages. Example of bills can be found in Figures VII and VIII, on the following pages. These figures include the charge for an IOL which was $823. This $1684+ fee for the three-hour outpatient visit does not include the $1200+ in surgeons' and anesthesiologists' fees which are billed separately. So lucrative is the outpatient procedure that many hospitals are advertising "no cost" cataract surgery for Medicare patients, in which they waive the patient's $400 Medicare deductible. This practice will be discussed in detail in Section II E.

4. Ambulatory Surgical Centers/Free-Standing Surgical Centers (ASC)

An alternative to the hospital inpatient and outpatient settings is the free-standing surgical center or ambulatory surgical center (ASC). These usually are surgical centers designed specifically for cataract surgery and lens implants, which are usually shared by a group of physicians. Medicare pays a maximum of $553 in facility fees plus the cost of the lens. The beneficiary is required to pay 20% of the cost of the IOL. The charges to Medicare for lenses is comparable to the outpatient cost, ranging from $300 to over $900.

5. Physician's Office

At present, a handful of physicians are performing cataract surgery on an outpatient basis in their own offices. There is no reimbursement for facility fees when the procedures are performed in the office. In such cases, the surgeon is reimbursed only for the IOL and his operating fees.

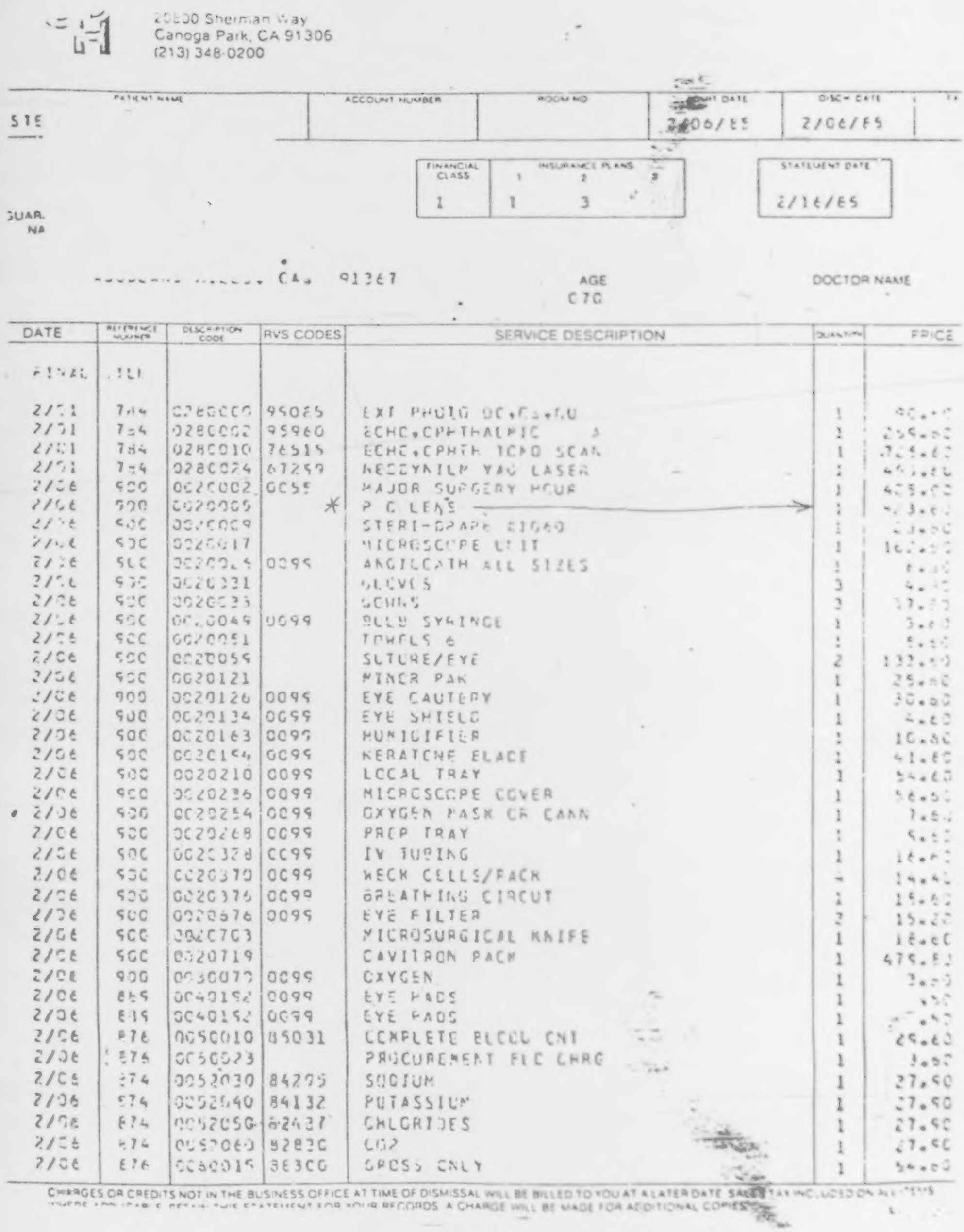
Table X

Percentage of Procedures Performed in Each Treatment Setting

	Physician's Office & ASC	Outpatient Hospital	Inpatient Hospital
1981	-	-	-
1985	7%	70%	23%
1986	10%	75%	15%
1987	12%	80%	8%
1988	13%	79%	8%
1989	14%	78%	8%
1990	15%	77%	[illegible]

Projections based on data that 5% of surgeons in 1983 performed opthalmic surgery in physician's offices or ASCs.

Figure VII



20500 Sherman Way
Canoga Park, CA 91306
(213) 348-0200

PATIENT NAME	ACCOUNT NUMBER	ROOM NO	ADMIT DATE	DISCH DATE
STE			2/06/85	2/06/85

FINANCIAL CLASS	INSURANCE PLANS 1	2	3	STATEMENT DATE
1	1	3		2/16/85

GUAR. NA

CA 91367

AGE 070

DOCTOR NAME

DATE	REFERENCE NUMBER	DESCRIPTION CODE	RVS CODES	SERVICE DESCRIPTION	QUANTITY	PRICE
FINAL	BILL					
2/01	784	0280000	95025	EXT PHOTO OC,CS,FU	1	40.00
2/01	784	0280002	95960	ECHO,OPHTHALMIC	1	259.50
2/01	784	0280010	76515	ECHO,OPHTH ICHO SCAN	1	725.60
2/01	784	0280024	67259	NEODYMIUM YAG LASER	1	463.80
2/06	900	0020002	0055	MAJOR SURGERY HOUR	1	405.00
2/06	900	0020005	*	P C LENS	1	423.60
2/06	900	0020009		STERI-DRAPE 21060	1	23.60
2/06	900	0020017		MICROSCOPE UNIT	1	162.00
2/06	900	0020025	0095	ANGIOCATH ALL SIZES	1	8.00
2/06	900	0020031		GLOVES	3	4.80
2/06	900	0020035		GOWNS	3	37.50
2/06	900	0020049	0099	BULB SYRINGE	1	3.00
2/06	900	0020051		TOWELS 6	1	9.50
2/06	900	0020059		SUTURE/EYE	2	132.00
2/06	900	0020121		MINOR PAK	1	25.60
2/06	900	0020126	0095	EYE CAUTERY	1	30.60
2/06	900	0020134	0099	EYE SHIELD	1	4.80
2/06	900	0020163	0099	HUMIDIFIER	1	10.80
2/06	900	0020154	0099	KERATONE BLADE	1	41.60
2/06	900	0020210	0099	LOCAL TRAY	1	54.60
2/06	900	0020236	0099	MICROSCOPE COVER	1	56.50
2/06	900	0020254	0099	OXYGEN MASK OR CANN	1	7.60
2/06	900	0020268	0099	PREP TRAY	1	9.50
2/06	900	0020328	0099	IV TUBING	1	16.60
2/06	900	0020370	0099	WECK CELLS/PACK	4	14.40
2/06	900	0020376	0099	BREATHING CIRCUT	1	15.60
2/06	900	0020676	0095	EYE FILTER	2	15.20
2/06	900	0020703		MICROSURGICAL KNIFE	1	18.60
2/06	900	0020719		CAVITRON PACK	1	479.80
2/06	900	0030073	0099	OXYGEN	1	3.00
2/06	869	0040152	0099	EYE PADS	1	.50
2/06	819	0040152	0099	EYE PADS	1	[illegible].50
2/06	876	0050010	85031	COMPLETE BLOOD CNT	1	29.60
2/06	876	0050023		PROCUREMENT FEE CHRG	1	3.50
2/06	874	0052030	84295	SODIUM	1	27.90
2/06	874	0052040	84132	POTASSIUM	1	27.90
2/06	874	0052050	82437	CHLORIDES	1	27.90
2/06	874	0052060	82830	CO2	1	27.90
2/06	876	0060015	86300	CROSS ONLY	1	54.60

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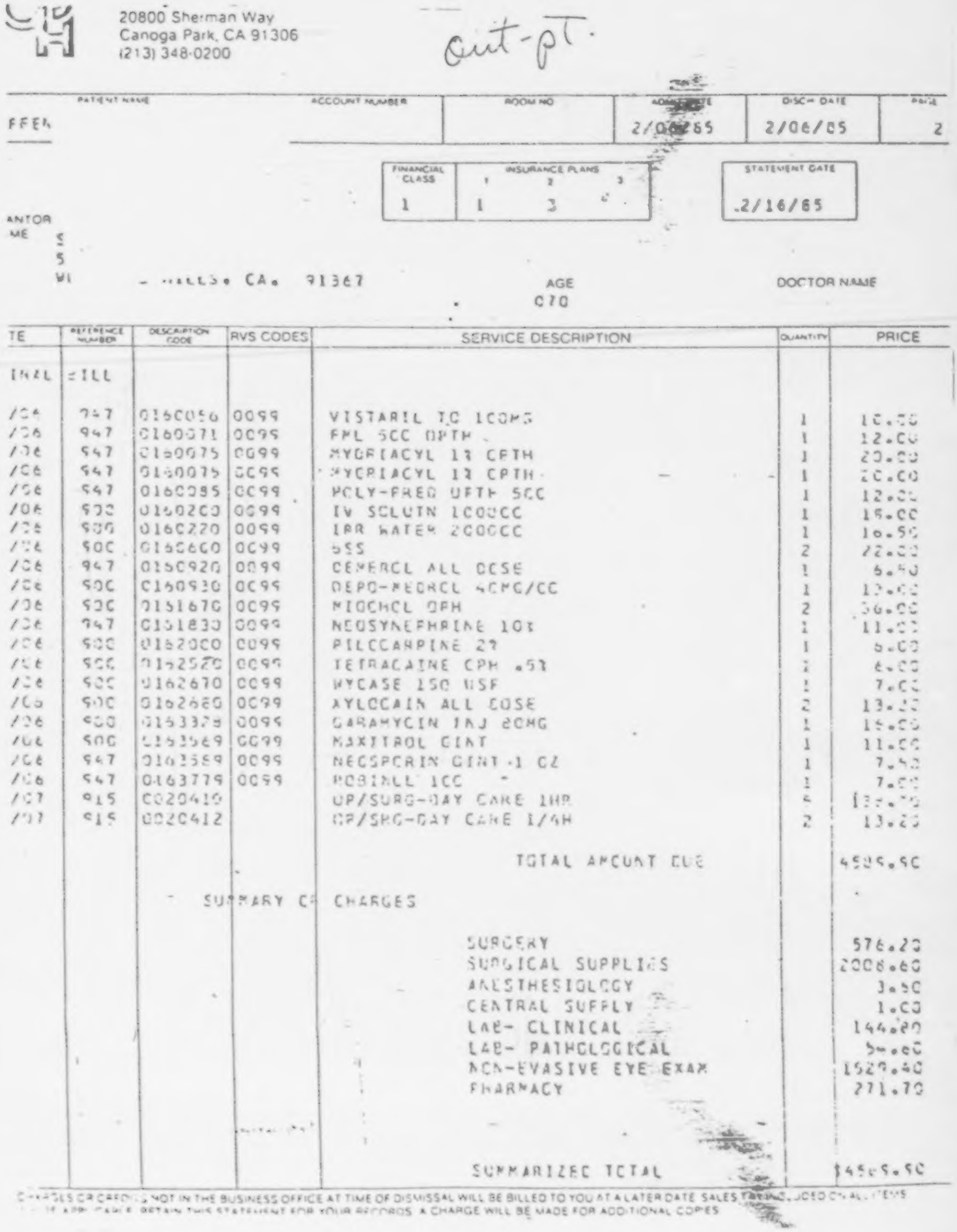
Figure VIII



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Out-pt.

PATIENT NAME	ACCOUNT NUMBER	ROOM NO	ADMIT DATE	DISCH DATE	PAGE
FFEN			2/06/85	2/06/85	2

FINANCIAL CLASS	INSURANCE PLANS 1	2	3
1	1	3	

STATEMENT DATE 2/16/85

ANTOR
ME S
5
WI - HILLS, CA. 91367

AGE 070

DOCTOR NAME

TE	REFERENCE NUMBER	DESCRIPTION CODE	RVS CODES	SERVICE DESCRIPTION	QUANTITY	PRICE
INAL	BILL					
/06	947	0160056	0099	VISTARIL IC 100MG	1	10.00
/06	947	0160071	0099	FML 5CC OPTH	1	12.00
/06	947	0160075	0099	MYDRIACYL 1% OPTH	1	20.00
/06	947	0160075	0099	MYDRIACYL 1% OPTH	1	20.00
/06	947	0160085	0099	POLY-PRED OPTH 5CC	1	12.00
/06	900	0160200	0099	IV SOLUTN 1000CC	1	15.00
/06	900	0160220	0099	IRR WATER 2000CC	1	16.50
/06	900	0160660	0099	BSS	2	22.00
/06	947	0160920	0099	DEMEROL ALL DOSE	1	6.40
/06	900	0160930	0099	DEPO-MEDROL 40MG/CC	1	13.00
/06	900	0161670	0099	MIOCHOL OPH	2	36.00
/06	947	0161830	0099	NEOSYNEPHRINE 10%	1	11.00
/06	900	0162000	0099	PILOCARPINE 2%	1	5.00
/06	900	0162520	0099	TETRACAINE OPH .5%	1	6.00
/06	900	0162670	0099	WYCASE 150 USP	1	7.00
/06	900	0162680	0099	XYLOCAIN ALL DOSE	2	13.20
/06	900	0163379	0099	GARAMYCIN INJ 80MG	1	15.00
/06	900	0163569	0099	MAXITROL OINT	1	11.00
/06	947	0163589	0099	NEOSPORIN OINT 1 OZ	1	7.50
/06	947	0163779	0099	ROBINUL 1CC	1	7.00
/07	915	0020410		OP/SURG-DAY CARE 1HR	4	[illegible]
/07	915	0020412		OP/SRG-DAY CARE 1/4H	2	13.20
				TOTAL AMOUNT DUE		4589.90

SUMMARY OF CHARGES

SURGERY	576.20
SURGICAL SUPPLIES	2008.60
ANESTHESIOLOGY	3.50
CENTRAL SUPPLY	1.00
LAB- CLINICAL	144.80
LAB- PATHOLOGICAL	54.60
NON-EVASIVE EYE EXAM	1529.40
PHARMACY	271.70
SUMMARIZED TOTAL	$4589.90

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Most experts predict that unless there is a policy change by HCFA or the Congress, 92% or more of all cataract surgery will be performed on a hospital outpatient basis by 1990. (See Table X, above) Hospitals have an incentive to keep their inpatient costs below the DRG level in order to stay in business and continue to provide services. Outpatient facilities, on the other hand, have been designed for maximum efficiency and minimal operating costs. They have reduced the two to three day hospital stay for inpatients to a three-hour hospital visit. Like the inpatient facilities, the outpatient facilities, often in the same hospitals, can purchase their lenses at volume discounts. Intuitively, one would think that these savings would be passed on to the patients and Medicare. This is not the case. Medicare under part B pays more, substantially more, for IOL implants performed in the hospital outpatient setting. Medicare is paying the hospitals about $1200 under DRG 39 for cataract surgery with IOL implants. These same hospitals are collecting several times this amount, as much as $4500, for the identical procedure using only 3 hours of hospital resources.

As mentioned earlier, standard quality IOLs can be purchased reasonably for as little as $90 by requiring manufacturers to bid on them. Medicare part B is reimbursing outpatient hospitals and ASCs between $300 and $900 per lens. This year for IOLs alone Medicare will overpay at least $160 million.

By allowing hospitals to receive much more money for performing outpatient IOL implants, HCFA is forcing cataract surgery into the more lucrative outpatient arena. This will dramatically alter the DRG system by raising inpatient hospital costs first by reducing the patient volume on which hospitals depend to keep their costs down, and second by leaving hospitals with extremely sick or frail patients. The DRGs were calculated based on the "typical" patient. These sick and frail patients are much more costly than the "typical" patient, and hospitals cannot afford to treat them under the current DRG system. Unless the Medicare law is changed there is no incentive to contain costs of this procedure which will waste at least $1.2 billion this year, and will lose many billions more.

Additionally, patients operated upon in an inpatient setting receive extra protection because Peer Review Organization review all cataract preadmissions. Hospitals have formal internal peer review and other safeguards to insure quality of care. To some extent, these safeguards exist in hospital outpatient settings, but they are much less prevalent in ASCs or non-hospital outpatients surgical locations.

C. Kickbacks, Discounts, Bonuses, and Rebates

Section 1877 of the Social Security Act makes it a felony to offer or solicit bribes, kickbacks or rebates in cash or in kind unless "the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider..." Although the law encourages industry promoted discounts on items such as IOLs, what is prohibited is the failure to disclose the discount and pass it on to the Medicare program.

The climate which stimulates kickbacks and other improper inducements relates directly to the price of the IOL and Medicare reimbursement practices relating to the IOL. It is worth repeating that the average price of an IOL reimbursed by the Medicare program in 1981 was $265. In 1985, it was $400. The manufacturing cost for an IOL is roughly $35-$50. Under the DRG system many hospitals have gone to competitive bidding, reducing IOL prices by as much as 50%, or less than $100 apiece. Where outpatient surgery is performed, there is no corresponding pressure to reduce IOL prices since under part B of Medicare, the insurance carrier pays the invoice price of the IOL which ranges from $300 to $750. It is obvious that the profit margins are very high and that some manufacturers are trying to stave off true competitive bidding by taking $50 or more out of their profits to "buy off" some physicians and gain a competitive edge.

Evidence of kickbacks and other improper inducements have been associated with the IOL industry for more than five years. From the Subcommittee's investigation, evidence and allegations of kickbacks and other illegal marketing practices are flagrant and inescapable. Inducements ranged from:

- outright payments of cash to physicians (in the form of a $50 to $70 deposit in a private account in the Cayman Islands) for each IOL purchased,
- "free stock" in the manufacturer,
- "free lasers" and other IOL surgery equipment,
- "donations" of one lens for every on a purchased,
- keys to resort condominiums,
- yachts, cars and houses,
- trips to Colorado, Europe, etc. for "medical" skiing seminars, and
- large payments for phony consultants.

Our investigation verified the judgement of one physician who told the Subcommittee, "The whole system is corrupt and is corrupting physicians, mostly I feel, out of ignorance — but of course greed is a big factor. Some very big names in ophthalmology are receiving large financial incentives to PR the companies implants. I'm happy to see you investigating this and though it casts a shadow on my profession — if we can stop the 20% or so who are unethical it may restore people's faith in my profession."

What is a Kickback?

Title 42, section 1395 of the U.S.Code defines a kickback as follows:

> (a) Whoever —
>
> (1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this subchapter.
>
> (2) at any time knowingly and willingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment.
>
> (3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantitiy than is due or when no such benefit or payment is authorized or
>
> (4) having made application to receive any such benefit or payment of the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment of any part thereof to a use other than for the use and benefit of such other person, shall (i) in the case of such statement,

representation concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this subchapter, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both.

(b)(1) Whoever knowingly and willingly solicts or receives any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which may be made in whole or in part under this subchapter, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof,shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person —

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

The existing kickback statute, detailed above, was modified in 1978 by Public Law 95-142. Based on congressional investigations demonstrating the impact of fraud, waste and abuse in clinical laboratories, Medicaid mills and nursing homes, penalties for kickbacks were extended from a misdemeanor to a felony. The legislative history of what constitutes a felony is more specific as to what constitutes a kickback:

> "Kickbacks take a variety of forms including cash long-term credit arrangements, gifts, supplies, and equipment, and the furnishing of business equipment."

Specific evidence of inproper inducements found by the Subcommittee have been or will be referred to the Inspector General of the U.S. Department of Health and Human Services for investigation. What follows is not exhaustive, but rather illustrative of the typical kinds of conduct brought to the Subcommittee's attention.

Direct Kickbacks

- Three ophthalmologists told the Subcommittee that they participated in direct kickback schemes in which they were given direct cash rebates from the manufacturers for every lens that they implanted.

- A well known surgeon, according to one investigation received 1600 free lenses in return for using his name in marketing the lens. He then billed Medicare $500 to each of these lenses. Medicare paid $80,000 too much just for IOLs.

- A California ophthalmologist told the Subcommittee that he declined to participate in a purchase arrangement commonly used by IOL manufacturers. He said, "A company offered me $70 per lens to be put into an account in my name in the Bahamas — I told him to ___ up a rope".

Indirect Kickbacks

The Subcommittee found the kickbacks are often disguised by salesmen as follows:

- Gifts of stock in the manufacturer;

- Use of a yacht;

- Discount of physicians for volume purchases of IOLs which are not made available uniformly to all physicians;

- Cash rebates to physicians who purchase from the company;

- Free IOLs provided by the manufacturer.

Of these mechanisms, the award of stock is commonly offered by IOL manufacturers, according to an ophthalmologist who told the Subcommitte he was offered such inducements for purchasing IOLs from the company.

A securities analyst with a investment firm verified the ophthalmologist's claims in a telephone conversation with the Subcommittee in April of 1985. She said, "One IOL company owned by doctors, blatantly offers stock and other inducements to doctors." She continued, "This cannot be reflected in lower Medicare prices." The American Academy of Ophthalmology, in a recent advisory opinion on their code of ethics, reported that receiving shares of stock in exchange or volume purchases of lenses is patently unethical. The advisory stated, "Not only would it be impossible to pass on to the cataract patient the fluctuating value of the stock received, a doctor could be easily seduced into a continuing loyalty to the company in question."

An ophthalmologist reported to the Subcommittee in July, 1985 that, "several years ago a company offered use of a yacht off Florida as an incentive to use their lenses."

Another ophthalmologist mentioned he was offered a "second"home — purchased by the company seeking his business.

One manufacturer informed the Administrator of a southern hospital that for every "ultraviolet absorbing IOL purchased at list price, a free "generic" posterior chamber lens would be donated to the hospital." (See letter dated 1984 outlining the proposal, in Figure IX.)

Business Equipment

The most common form of inducement offered is surgical and/or other equipment commonly used by an ophthalmologist. Such equipment often includes:

YAG Lasers. Lasers come in handy if a posterior implant patient finds that the capsule around his/her new lens has clouded up, something that happens about half the time. By focusing the laser on the capsule, the physician can tear a hole in the membrane,-much like pulling a curtain back from a window, and restore vision. Lasers can cost as much as $80,000-$90,000 to purchase. (Manufacturers cost is $8,000)

Surgical accessories or surgical packs. Surgical accessories commonly include a disposable syringe filled with Healon or other clear liquids which help maintain the shape of the eye during surgery, and disposable sponges and knives. The pack is worth abut $75.

Phacoemulsification machines are devices which use ultrasound vibrations to turn cataracts into a jelly-like substance before extraction. They cost around $1000 per month to lease, or about $35,000 to purchase.

In most cases, the equipment mentioned above is essential to cataract surgery and follow-up care. Questions of concern arise, however, when such equipment if offered as an inducement to do business with a particular IOL manufacturer without consideration of what would be in the best interest of the patient or without reflecting those savings to the Medicare program. Furthermore, tax laws may be violated because hospitals and doctors are encouraged by manufacturers to take depreciation and investment tax credit on equipment that they really did not buy.

The legitimacy of these concerns was documented extensively in the Subcommittee's investigation.

According to the Executive Director of the American Intraocular Implant Society, in a recent Barron's interview, "how is a hospital supposed to reflect a YAG laster when they're getting a flat fee?"

This official takes a stern view of any form of discount which cannot be reflected in bills and said he is well aware of the problems of kickbacks in the IOL business. "I get calls all the time from doctors who asked me if they can accept a YAG laser. I tell them, 'Pay for the damn thing yourself.'" He said physicians also asked whether they can accept free surgical packs. "Our position is that any savings to a hospital or a doctor must absolutely be reflected in their bills."

A former President of the Amercain Intraocular Implant Society, addressed the notion that some programs seem designed by the manucfaturers to facilitate criminal

Figure IX

, 1984

Administrator
Hospital

Dear

The following is a purchase agreement for the sale of intraocular lenses to Hospital.

Prices are only for lenses purchased and used by that hospital. This agreement is voided by the distribution of products by Hospital to other facilities.

Prices are guaranteed for a period of one year starting December 1, 1984 and terminating November 30, 1985.

will initiate a consignment of lenses at that hospital.

PLAN A

With each ultraviolet absorbing IOL purchased from at list price, a ~~free "generic" posterior~~ chamber lens will be donated to Hospital. These generic lenses include catalog series .01, .02, 00, and .04. -loop, lens, and UV lenses are not included in the styles eligible for free lenses.

Free lenses will be reimbursed on a monthly basis.

PLAN B*

will sell IOLs to Hospital at the following prices:

Styles 00, .01, .02, .04 (generic)	$232.50 each
PLUS one free I/A tube-set with each purchased lens	-32.50 value
PLUS one free pair of UV post-op goggles with each lens	- 5.00 value
	$195.00 net cost

Figure IX (cont.)

Style UV series (ultraviolet absorbing lens)	$280.00
PLUS one free I/A tube set	-32.50
PLUS one free pair of UV goggles	- 5.00
	$242.50 net cost

*There are no minimum usage requirements with PLAN B.

PLAN C

will sell IOLs to Hospital at the following prices, providing the minimum monthly ordering quantities are observed.

Minimum of 50 lenses/month*

Generic styles 00, 01, 02, 04	$170.50 each
UV style posterior chamber lenses	262.50 each

Minimum of 75 lenses/month*

Generic styles 00, 01, 02, 04	$155.00 each
UV style posterior chamber lenses	245.00 each

Minimum of 100 lenses/month*

Generic styles 00, 01, 02, 04	$139.50 each
PLUS one free UV post-op goggle	-5.00
	$134.50 net cost
UV style posterior chamber lenses	$199.50 each
PLUS one free UV post-op goggle	-5.00
	$194.50 net cost

*Lenses ordered can be mixed in any quantities or product styles.

RESIDENT PROGRAM

is extremely committed to the education growth of Ophthalmology residents. Upon initiation of PLANS A, B, or C, will provide a $5,000 fund for use by the residents of the University for the following uses: travel to and from major meetings, travel and/or honorariums for guest lectures, other educational reasons approved by

This fund can be renewed annually. The fund will be maintained by and withdrawals must be requested in writing.

Figure IX (cont.)

BONUS - When the first two hundred lenses are reordered from the consignment, the Video Textbook of Cataract Surgery (see attachment) will be donated to the Residency Program. This excellent teaching tool is valued at $800.

Warmest personal regards,

deception by surgeons and reimbursers. "If you get a free piece of equipment, how can you prorate that free piece of equipment onto the cost of each cataract operation which you put an IOL in and show that discount to Medicare? I don't know how you can do that."

- A Maryland ophthalmologist wrote the Subcommittee that an IOL company offered to provide a free phacoemulsifier to his center if they agreed to use a certain number of their IOLs. His department declined.
- A South Dakota doctor was offered over $95,000 worth of equipment in exchange for a 3-year commitment to use IOLs from a particular manufacturer. He was also offered a camera and VCR. He told the Subcommittee, "I was told that this inducement was approved by Medicare and the American Implant Society and that I would get an investment tax credit on the equipment. All of this is untrue, I realize. Now tell me, how am I going to get an investment tax credit on equipment I didn't purchase and Medicare essentially pays for?"
- The vast majority of ophthalmologists responding to a June, 1985, Subcommittee questionnaire reported they were offered equipment at discount or free, including lasers, cameras, VCRs, slit lamps, etc. some of which is related to cataract surgery and some of which is not.

Travel and Training

Another common inducement made by IOL manufacturers to agreeable doctors involved the arrangement of travel on the pretext of "training seminars." According to the American Academy of Ophthalmology's (AAO) code of ethics, such "customer appreciation plans" under which they invite all ophthalmologists who purchase ..(a quantity).. of lenses in any year to be guests of the IOL manfacturees for an all-expenses-paid week long meeting of the IOL manufacturer in the Bahamas..." is simply a bribe or a kickback. As stated in the AAO's code of ethics: "Window dressing seminars do not transform a free vacation in the Bahamas into a scientific conference which is paid for by the ophthalmologist ..."

In spite of the AAO warnings, such inducements abound in the industry three ophthalmologists told the Subcommittee that IOL salesmen told them they would be awarded vacations for purchasing a certain number of IOLs.

Telephone conversations between Subcommittee staff and a number of ophthalmologists revealed that companies offer travel in Europe in appreciation of the purchase of a large volume of IOLs.

A Counsel for the American Intraocular Implant Society reported to the Subcommittee, "Many doctors have complained to me about certain companies (names deleted) using "studies" as excuses to provide doctors who use their lenses with free trips."

Again, it is important to note that free travel is not automatically illegal for the lens manufacturer to provide or for the implant surgeon to receive, as long as they are reflected in reimbursement claims. According to the American Intraocular Implant Society, however, such bonuses raise serious legal and ethical questions and should be avoided.

Paid IOL Investigators

The principal barrier to entry in the IOL market is FDA approval of IOLs (see Section VI A for further detail). This has not been a major problem because of a special provision in the IOL device law which allows distribution of IOLs to qualfied surgeons on an almost unlimited basis prior to approval. In order to use the lens, a surgeon agrees to serve as an "investigator" for an IOL manufacturer and track patients who have the IOL inserted (called a "core" study). The doctor is paid compensation for his work by the manufacturer. Literally every board certified ophthalmologist is eligible to participate in this investigative process.

In a perversion of the FDA process, some IOL manufacturers are using the FDA approval process as an excuse to "buy off" surgeons. Manufacturers are paying very large amounts for paperwork preparation and also designating some doctors as adjunct investigators and paying them for essentially nothing but the use of the manufacturer's lens.

This legal form of "kickback," sanctioned by current FDA law, works essentialy as follows: The FDA requires a "core" study of 500 patients to be followed over one year. This means a manfacturer has to arrange for 800-1,000 patients to be treated by about 25-50 doctors. The doctors can be paid for acting as an "investigator" and filing 6 brief reports on each patient. Some manufacturers pay cash; some give free lenses. One free lens ($300) is roughly about value for total work done on one patient. Many manufacturers pay far in excess of this. They are really bribing doctors.

FDA also allows "adjunct" study beyond core requirements. There is no paperwork involved; FDA admits they don't use the data submitted. By applying for adjunct status, a manufacturer can sell lenses to these "investigators" without FDA final approval. This is another vehicle for bribery. Furthermore, some manufacturers are expanding their studies to thousands as a way to use FDA as a legal excuse to make high payments etc. to doctors using their lenses.

Sale and Resale of IOLs by Surgeons

A more sophisticated and subtle form of improper inducements exists in the sale and resale of IOLs by surgeons and referral they make to individuals and hospitals who will use these IOLs.

One scheme involves surgeons purchasing the lenses they use directly from the manufacturers, and then reselling the IOLs to the hospitals, who then bill Medicare directly. Medicare reimburses the hospital based upon their costs, which in many cases are considerably more than the surgeon paid for them. The surgeon may mark up the lens directly, or he may participate in any one of a number of discount or rebate schemes, which provide him with financial incentives which do not show up on the invoice.

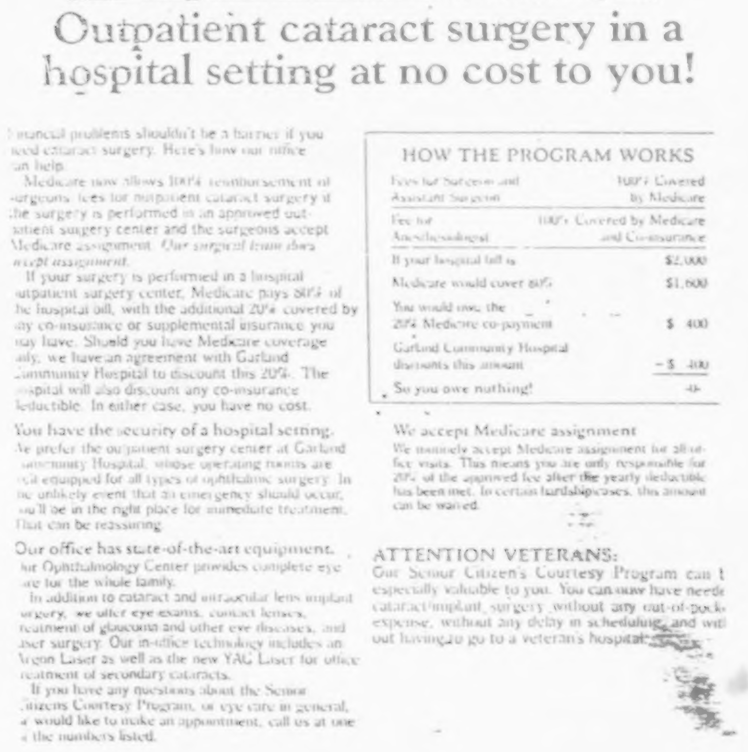
Surgeons may profit even without purchasing the lenses directly. Manufacturers offer the same "bribes" to ophthalmologists who have the hospitals order the manufacturer's lenses. This makes the Medicare overpayments even more difficult to track down.

E. "No Cost" Advertisements

In recent months, advertisements offering "no cost" cataract surgery to Medicare patients have been apearing in magazines, newspapers, and mailboxes around the country. "No cost" cataract surgery is not free; Medicare winds up footing the entire bill, while the facilities and physicians waive the patient's deductible. "No cost" cataract surgery is of no cost only to the patients.

The ad below explains how "no cost" cataract surgery works. According to the ad, Medicare now allows 100% reimbursement of surgeon's fees for outpatient cataract surgery if the surgery is performed in an approved outpatient surgery center and the surgeon accepts Medicare assignment. Medicare pays 80% of the hospital bill, with the patient or his coinsurance responsible for the remaining 20%. Many hospitals waive or discount this 20%, saving the patient $400 or more in out of pocket expenses. One hospital reported increasing business by over 11% and annual revenue by over $100,000 after instituting a "no cost" surgical program.

One California hospital did a cost-benefit analysis after instituting "no cost" cataract surgery and sending out brochures to 9000 area residents in a direct mail advertising campaign. Cataract surgery cases at the hospital increased by 11%, but the number of Medicare patients increased by 15%. Now over 90% of the hospitals cataract patients are covered by Medicare. Previously the hospital had been reimbursed $1463 per case under the DRG for inpatient surgery. Under the "no cost" scheme they are collecting $1490 per case, and that is without incurring the 24-hour nursing costs associated with inpatient surgery. In addition, 80% of their patients had supplementary private insurance and the hospital was able to collect a major portion of the patient's $601 coinsurance and deductible. In short, for every dollar the hospital spent for its mail campaign, they increased revenues by over $30.



Introducing the Senior Citizens Courtesy Program:

Outpatient cataract surgery in a hospital setting at no cost to you!

inancial problems shouldn't be a barrier if you eed cataract surgery. Here's how our office an help.

Medicare now allows 100% reimbursement of urgeons' fees for outpatient cataract surgery if he surgery is performed in an approved outpatient surgery center and the surgeons accept Medicare assignment. *Our surgical team does accept assignment.*

If your surgery is performed in a hospital utpatient surgery center, Medicare pays 80% of he hospital bill, with the additional 20% covered by ny co-insurance or supplemental insurance you nay have. Should you have Medicare coverage nly, we have an agreement with Garland Community Hospital to discount this 20%. The ospital will also discount any co-insurance eductible. In either case, you have no cost.

You have the security of a hospital setting.

We prefer the outpatient surgery center at Garland Community Hospital, whose operating rooms are well equipped for all types of ophthalmic surgery. In he unlikely event that an emergency should occur, ou'll be in the right place for immediate treatment. That can be reassuring.

Our office has state-of-the-art equipment.

ur Ophthalmology Center provides complete eye are for the whole family.

In addition to cataract and intraocular lens implant urgery, we offer eye exams, contact lenses, reatment of glaucoma and other eye diseases, and aser surgery. Our in-office technology includes an Argon Laser as well as the new YAG Laser for office reatment of secondary cataracts.

If you have any questions about the Senior Citizens Courtesy Program, or eye care in general, or would like to make an appointment, call us at one of the numbers listed.

HOW THE PROGRAM WORKS

Fees for Surgeon and Assistant Surgeon	100% Covered by Medicare
Fee for Anesthesiologist	100% Covered by Medicare and Co-insurance
If your hospital bill is	$2,000
Medicare would cover 80%	$1,600
You would owe the 20% Medicare co-payment	$ 400
Garland Community Hospital discounts this amount	– $ 400
So you owe nothing!	-0-

We accept Medicare assignment

We routinely accept Medicare assignment for all office visits. This means you are only responsible for 20% of the approved fee after the yearly deductible has been met. In certain hardship cases, this amount can be waived.

ATTENTION VETERANS:

Our Senior Citizen's Courtesy Program can t especially valuable to you. You can now have neede cataract/implant surgery without any out-of-pock expense, without any delay in scheduling, and wit out having to go to a veteran's hospital.

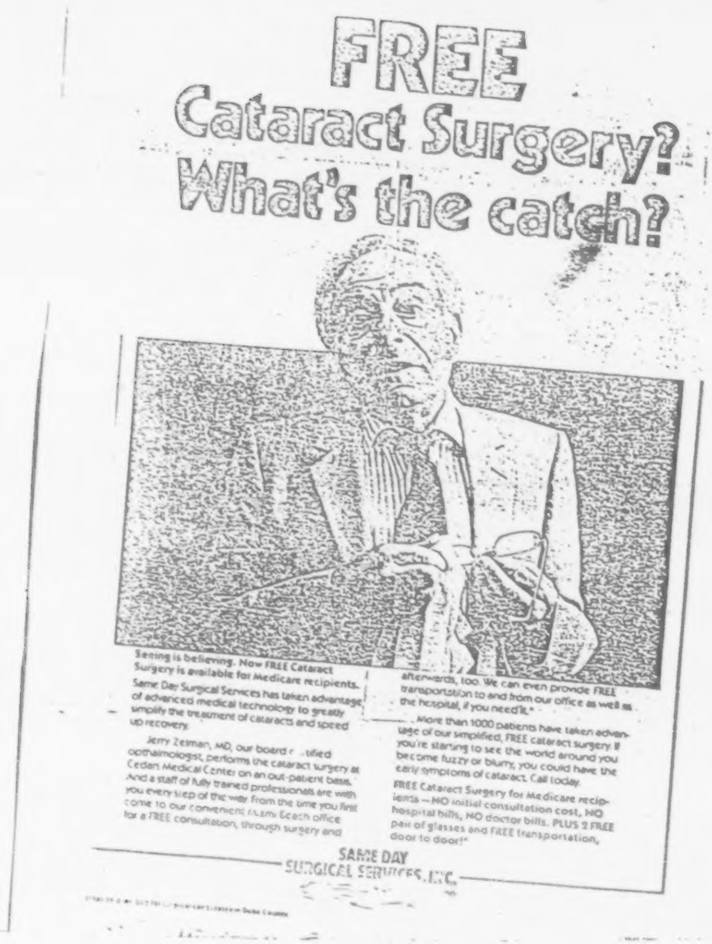
There is no prohibition against waiver of deductible and coinsurance by a provider of services. This ability to waive copayments applies to both inpatient and outpatient service and is not affected by whether the provider receives cost-based reimbursement or prospective payments. However, the provider, and not Medicare, must bear the beneficiary's liability. For purposes of determining Medicare payment, the provider must bill its intermediary as if the patient were billed for the appropriate deductible coinsurance amounts which are deducted from the prospective payments. Under cost reimbursement, these amounts must be included on the provider's cost report for the determination of final payment for the year. The provider may not claim as a bad debt amounts for which it assumed the beneficiary's liability. A provider's waiving of payment from the beneficiary should have no effect on Medicare payments. Unfortunately, this has not been the case.

Current Medicare program instructions indicate that a billed amount that is not reasonably related to an expectation of payment should not be considered the "actual" charge for processing a current claim. What this means is that if hospitals and physicians set charges for services, fully intending to waive the patients deductible and coinsurance, they are in violation of the law if they submit those set charges to Medicare as the "actual" charges.

The ads on the following pages, collected from newspapers around the country, are representative of this widespread fraudulent practice. "No cost" cataract surgery is responsible for millions of dollars in Medicare overpayments. Hospitals are inflating their charges to Medicare by an amount equal to or greater than the patients coinsurance and deductible, with the full intention of waiving the patient's costs and having Medicare foot the entire bill. Not only are these hospitals openly violating the congressional intent of the Medicare system, HCFA is condoning their actions by failing to take action against them.

Waiver of beneficiary copayments represents a clear disregard for Medicare and the philosophy behind Medicare coinsurance and deductibles. The Medicare program requires patients to share in the cost of their health care for a number of important reasons. First, this cost sharing reduces the portion Medicare must pay,which would otherwise be financed through taxes and other sources. Cost sharing also reduces, but does not eliminate, the need for administrative control over the use of medical services by providing a financial incentive to patients and providers to choose more economical forms of care.

The Subcommittee would in fact support the charitable waiving of copayments for those elderly to whom this represents a burden. It cannot, however, condone the waiving of coinsurance when done explicitly to entice unneeded cataract surgery or as a method of bilking the Medicare program.



FREE Cataract Surgery? What's the catch?

Seeing is believing. Now FREE Cataract Surgery is available for Medicare recipients.

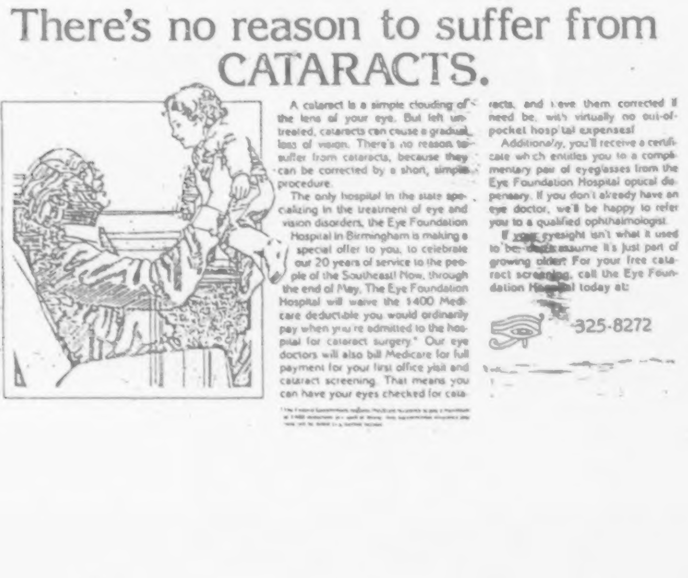
Same Day Surgical Services has taken advantage of advanced medical technology to greatly simplify the treatment of cataracts and speed up recovery.

Jerry Zeiman, MD, our board certified opthalmologist, performs the cataract surgery at Cedars Medical Center on an out-patient basis. And a staff of fully trained professionals are with you every step of the way from the time you first come to our convenient Miami Beach office for a FREE consultation, through surgery and afterwards, too. We can even provide FREE transportation to and from our office as well as the hospital, if you need it.*

More than 1000 patients have taken advantage of our simplified, FREE cataract surgery. If you're starting to see the world around you become fuzzy or blurry, you could have the early symptoms of cataract. Call today.

FREE Cataract Surgery for Medicare recipients — NO initial consultation cost, NO hospital bills, NO doctor bills. PLUS 2 FREE pair of glasses and FREE transportation, door to door!*

SAME DAY SURGICAL SERVICES, INC.



There's no reason to suffer from CATARACTS.

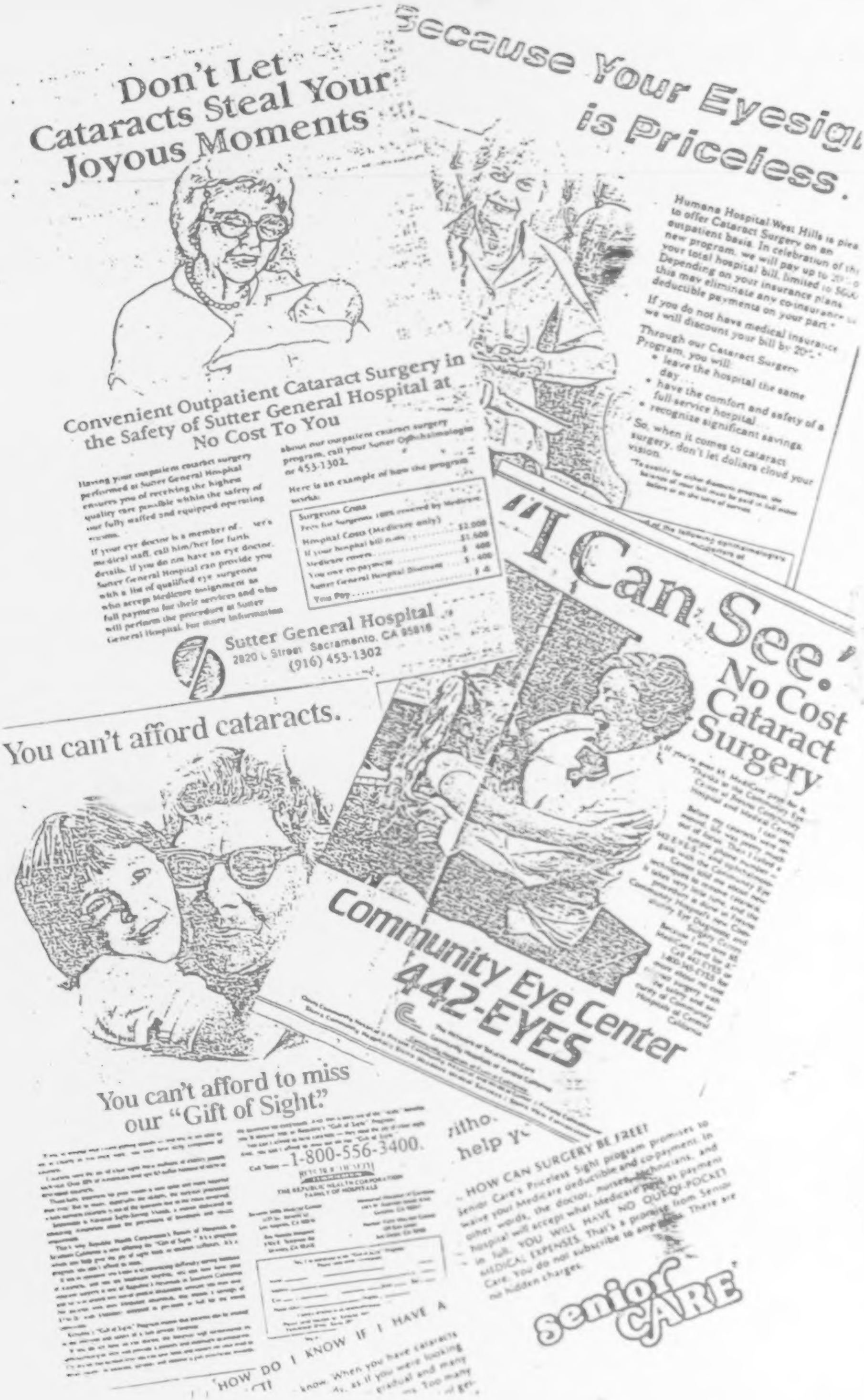
A cataract is a simple clouding of the lens of your eye. But left untreated, cataracts can cause a gradual loss of vision. There's no reason to suffer from cataracts, because they can be corrected by a short, simple procedure.

The only hospital in the state specializing in the treatment of eye and vision disorders, the Eye Foundation Hospital in Birmingham is making a special offer to you, to celebrate our 20 years of service to the people of the Southeast! Now, through the end of May, The Eye Foundation Hospital will waive the $400 Medicare deductible you would ordinarily pay when you're admitted to the hospital for cataract surgery.* Our eye doctors will also bill Medicare for full payment for your first office visit and cataract screening. That means you can have your eyes checked for cataracts, and have them corrected if need be, with virtually no out-of-pocket hospital expenses!

Additionally, you'll receive a certificate which entitles you to a complimentary pair of eyeglasses from the Eye Foundation Hospital optical dispensary. If you don't already have an eye doctor, we'll be happy to refer you to a qualified ophthalmologist.

If your eyesight isn't what it used to be, don't assume it's just part of growing older! For your free cataract screening, call the Eye Foundation Hospital today at:

325-8272



Don't Let Cataracts Steal Your Joyous Moments

Convenient Outpatient Cataract Surgery in the Safety of Sutter General Hospital at No Cost To You

Having your outpatient cataract surgery performed at Sutter General Hospital ensures you of receiving the highest quality care possible within the safety of our fully staffed and equipped operating rooms.

If your eye doctor is a member of [illegible]ter's medical staff, call him/her for furth[er] details. If you do not have an eye doctor, Sutter General Hospital can provide you with a list of qualified eye surgeons who accept Medicare assignment as full payment for their services and who will perform the procedure at Sutter General Hospital. For more information about our outpatient cataract surgery program, call your Sutter Ophthalmologis[t] or 453-1302.

Here is an example of how the program works:

Surgeons Costs
Fees for Surgeons 100% covered by Medicare.
Hospital Costs (Medicare only)
If your hospital bill totals $2,000
Medicare covers $1,600
You owe co-payment .... $ 400
Sutter General Hospital Discount .... $-400
You Pay .... $-0-

Sutter General Hospital
2820 L Street Sacramento, CA 95816
(916) 453-1302

Because Your Eyesig[ht] is Priceless.

Humana Hospital West Hills is plea[sed] to offer Cataract Surgery on an outpatient basis. In celebration of th[is] new program, we will pay up to 20[%] o[f] your total hospital bill, limited to $6[00]. Depending on your insurance plans, this may eliminate any co-insurance or deductible payments on your part.*

If you do not have medical insurance, we will discount your bill by 20%.*

Through our Cataract Surgery Program, you will:
- leave the hospital the same day . . .
- have the comfort and safety of a full-service hospital . . .
- recognize significant savings.

So, when it comes to cataract surgery, don't let dollars cloud your vision.

*To qualify for either discount program, the balance of your bill must be paid in full either before or at the time of service.

[illegible] of the following ophthalmologists [illegible]

"I Can See." No Cost Cataract Surgery

If you're over 65, MediCare pays for it. Thanks to the Community Eye Center at Fresno Community Hospital and Medical Center, I can see.

[illegible]

Community Eye Center
442-EYES

You can't afford cataracts.

You can't afford to miss our "Gift of Sight."

Call Today — 1-800-556-3400.

THE REPUBLIC HEALTH CORPORATION FAMILY OF HOSPITALS

HOW CAN SURGERY BE FREE?

Senior Care's Priceless Sight program promises to waive your Medicare deductible and co-payment. In other words, the doctor, nurses, technicians, and hospital will accept what Medicare pays as payment in full. YOU WILL HAVE NO OUT-OF-POCKET MEDICAL EXPENSES. That's a promise from Senior Care. You do not subscribe to any [illegible]. There are no hidden charges.

senior CARE

HOW DO I KNOW IF I HAVE A [illegible]

[illegible] know. When you have cataracts [illegible] as if you were looking [illegible] gradual and many [illegible]. Too many [illegible]

III. A SURVEY OF OPHTHALMOLOGISTS REGARDING THEIR EXPERIENCES WITH FRAUD, WASTE AND ABUSE IN THE AREA OF CATARACT SURGERY

As a part of its comprehensive review of Medicare cataract surgery, the Subcommitee sought to systematically gather the opinions of those directly providing this service. Subcommittee staff had meetings, telephone conversations and written correspondence with, among others, physicians performing cataract surgery, the professional associations which represent ophthalmologists, IOL manufacturers and their sales representatives, and hospital officials. The Chairman also conducted a national random survey of ophthalmologists performing cataract surgery and of the industry manufacturing IOLs.

Information from providers confirmed other evidence gathered by the Subcommittee of the widespread nature of fraud, waste, and abuse surrounding cataract surgery and in particular the sale of intraocular lenses.

In June, 1985, the Chairman mailed a survey to a statistically valid random sample of doctors performing cataract surgery in the United States. This survey asked ophthalmologists a series of questions focusing on marketing practices and purchasing agreements in the sale of intraocular lenses. (See Appendix A). Doctors from around the nation, representing nearly one million patients, responded to the Chairman's survey.

While most of those doctors responding to the survey indicated that they themselves were not involved in such practices, many reported to the Subcommittee that they were familiar with a number of questionable and/or illegal purchasing arrangements employed by IOL manufacturers/sales representatives. Many doctors reported being aware of:

- awards of vacations to physicians for purchasing a certain number of IOLs,
- gifts of stock in the manufacturing company to physicians who purchase a number of lenses
- cash rebates to physicians who purchase lenses,
- free IOLs for purchase of a certain number of IOLs, and
- progressive discounts for volume orders.

Other doctors reported having knowledge of specific offers made to peers by IOL manufacturers and/or their sales representatives for the purchase of certain numbers of their lenses including:

- purchasing of second homes for doctors,
- cash payments of up to $150 per lens purchased,
- use of a yacht off the coast of Florida,
- free phacoemulsifiers (valued at approximately $35,000), and
- free vitrectomy machines (valued at approximately $20,000).

While most doctors responding to the Subcommittee survey indicate that such practices are not offered by manufacturers with which they do business, roughly one third reported that they knew of such offers by their manufacturers. Additionally, roughly one third of the ophthalmologists responding to the survey reported having at one time or another declined participation in purchase arrangements such as those above.

The Subcommittee questionnaire also asked ophthalmologists whether they considered these types of purchasing arrangements to be improper or illegal inducements. Over two thirds of the respondents did consider such practices kickbacks, bribes, or something otherwise improper. Many also remarked on what they felt to be the unethical nature of such practices.

One third of the doctors responding told the Subcommittee that they did not consider these arrangements to be kickbacks, bribes, or other improper inducements. The majority of doctors responding in this manner considered these purchase agreements legitimate business offerings. Said one doctor, "It's the American way... You get what you can." Another responded, "Incentives are used by everyone to sell as encouragement to go a particular direction. Even my preacher cajoles, 'Come to church and go to heaven. Would you consider that a bribe?"

Ophthalmologists were asked whether they felt that IOL manufacturers and/or sales representatives should be free to offer incentives to physicians to purchase a particular brand of lens. A two-thirds majority of those doctors responding told the Subcommittee that this should not be allowed. One doctor replied, "We should purchase the lens we feel is best for use, not financially best for us." Another stated that such offerings "compromise quality of care." Still another felt these practices "cheat Medicare and the patients."

One third of the responding doctors felt that manufacturers and their representatives should be free to offer incentives. Some expressing this viewpoint felt strongly about their rights in a competitive market. One doctor told the Subcommittee, "Since medicine and physicians are now expected to be merchants, why not the same low standard of ethics as car salesmen?"

During the course of its investigation the Subcommittee was contacted by a number of provider representatives expressing concern over what they considered illegal or unethical inducements in the sale of IOLs. Knowledge of the existence of such practices within the ophthalmology profession is extensive. This spring one professional association held a symposium with a keynote address by the president of the group entitled, "Marketing Practices and Rebates That are Occurring and are Continuing to Occur, and Your Responsibility and Your Vulnerability." The president continues, "Discounts, rebates and bonuses have recently taken many forms ... free lenses ... free equipment ... cash payments ... Some of these programs seem designed by the manufacturers to facilitate criminal deception by surgeons to reimbursers ... To profit illegally from discounts, rebates or bonuses by failing to report them to government reimbursers ... subjects the entire profession to injury. These practices amount to welfare cheating."

The Subcommittee has been contacted by provider representatives who have been shocked by the nature and extent of kickback and bribe offerings and acceptances related to Medicare cataract surgery. One hospital representative stated, "IOL manufacturers and their sales representatives are committing wholesale fraud."

IV. A SURVEY OF THE IOL INDUSTRY REGARDING THEIR EXPERIENCES WITH FRAUD, WASTE AND ABUSE IN THE AREA OF CATARACT SURGERY

The Subcommittee also sent questionnaires to manufacturers of intraocular lenses. These surveys asked manufacturers a series of questions centering around their marketing practices surrounding the sale of IOLs. (See Appendix B) Among the areas of inquiry contained in the Subcommittee questionnaire were the basis of earnings of their sales representatives (salary and/or commission), incomes of the manufacturers and their sales representatives, types of marketing practices used and the reasons for using such practices, and manufacturer opinions as to the legelity of properness of offering certain inducements for the purchase of a particular brand of IOLs.

As of this writing, the Subcommittee has received responses from 7 manufacturers with total 1984 gross sales of intraocular lenses of over $80 million. These companies employ marketing staffs made up primarily of sales representatives averaging 45 full time workers.

Responses to the Subcommittee survey indicate that IOL sales representatives earn large salaries and that most work strictly on a commission basis. Average salaries of those selling IOLs for the 7 responding manufacturers range from $35,000 to $90,000. Six of the seven companies employ their salesmen on a commission basis only.

The majority of manufacturers responding indicated to the Subcommittee that they had knowledge of a range of marketing plans including the offering of free equipment, company stock, vacations, cash rebates and volume discounts. Several of the respondents provided the Subcommittee with lists of those of their competitors they suspect or know use these practices. The majority of these respondents indicated their distaste for such practices.

Several of the companies did indicate that they offer volume discounts and purchase credit plans, but that they instruct those doctors and hospitals taking part in these offers to indicate the reception of these discounts on their Medicare bills.

The IOL industry is a very competitive one. When asked why manufacturers employed these sales techniques, most companies responded that this was a necessity of the competitive marketplace. One large manufacturer responded, "The IOL industry is very competetive. Because of this competition, manufacturers work hard to be the supplier of choice. Because most manufacturers hold high product quality standards, manufacturers also compete with service, convenience, image and price." Another company indicated the corresponding pressure on a company to offer inducements, "A company which does not offer such discounts would likely lose the customer."

During the course of its investigation, the Subcommittee was regularly contacted by members and representatives of the IOL industry. Subcommittee staff conversations with sales representatives wishing to remain anonymous for fear of retribution provided a good deal of candid information. These salespersons described literally hundreds of instances of kickbacks and bribes and other schemes offered by themselves and their competitors. The most common of these inducements came in the form of cash rebates per lens (up to $150) going toward the purchase of durable medical equipments such as lasers and microscopes. One sales representative called this practice "Green Stamping," likening it to the collecting of stamps to purchase a gift when you have enough collected. These representatives also described schemes invoving free trips to Hawaii, paying for architects to design surgical centers, and even free vacation homes.

These anonymous salespersons also related to the Subcommittee stories of training sessions employed by certain manufacturers. "Ask them (doctors and hospitals) what it will take for them to buy from and give it to them. It doesn't matter what it takes," one salesperson reported being instructed in a training session by a previous employer.

The problem of fraud and abuse is a growing one according to most of those salespersons confiding with the Subcommittee. "It's just like the 55 miles per hour speed limit," commented one representative. "Doctors see their peers doing it, profiting from it and not getting punished, so they say 'Why not me?'"

V. A CANDID CONVERSATION WITH AN IOL SALESMAN

Reprinted below is an excerpt from an interview between three sellers of ophthalmology supplies and equipment, including intraocular lenses, and an ophthalmologist. Because receipt of this tape was conditioned on confidentiality, names and specific references have been omitted or changed to protect participants' identities. The salesmen are employed by one of the country's largest suppliers of ophthalmlogy goods. This conversation took place in May and June, 1985.

Enticements

Salesman: What we do, Dr. (name omitted), we establish a competitive price. And we take a portion of that price ... counts for more than let's say half of the lenses and give it back to you as purchase credits — so that you can apply it towards this, you can apply it toward (brand name omitted) ... well, another example. We have a video system right now — I don't know if you've got a video camera on your scope or not — it's a hell of a system ... The camera alone usually sells for $8495. Right now the camera's on for $6995. You can get a VCR, a monitor and a stand that it all fits on for $8495. So in essence you're getting about $1500 worth of video equipment at no charge. That's going to be on a limited time basis.

The Pitch

Salesman: ...what we need to do is sit down with you and get some figures from you so we can put together a package and start talking — and say, here are your equipment needs, here's basically how you can finance over the next 1, 2, 3 years.

What we came up with is a financing program that's based upon you using our consumables, okay? Since we have capital equipment on one side, which is state of the art and pretty much the industry standard, and then we have high quality consumable products, such as IOLs, contact lenses and pharmaceuticals, we put the two of them together to come up with a financing program so that you can high tech your office or get that capital equipment that you need without any cash outlay. Now, one of the reasons that we can do this is in the past we'd always been calling on hospitals, doctors' offices, pharmacy — all these different places. Now all of a sudden we can call on one facility like yours — an ASC — and sell all our products at that one point. We call it single point distribution, okay? By us being able to sell a lot of products to one facility like yours, we're able to lower our cost to serve — cost to serve the manufacturer, marketing, and so on down the line. Well, when we lower our cost to serve, we increase revenues. One of the ways we're using increasing revenues is giving it back to you in the form of earned purchase credits. Now earned purchase credits are credits based upon the gross profit margin of each item that you buy from us. So, take as an example, if you bought a (brand name omitted) lens from us, you'd earn a purchase credit on that, so you know that might be $2.50 or something. What we're doing is we're looking at earned purchase credits on all the products that you can buy from (company name omitted) — from that consumable side — the disposables, the IOLs, the contact lenses, pharmaceuticals.

Additional Benefits

Doctor: Okay, you say you can get investment tax credit right up front, entitled to it, right?
Salesman: Yep.
Doctor: And depreciation on it?
Salesman: Yep.

Purchase Credits: One Doctor's Arrangement

Salesman: So you're at $27,000 the first year, $31.8 (thousand) the second and $36.6 the third.
Second Salesman: For a total of $95,760. Now let me explain how you can use that. What we've done is we've projected out what you would earn over the next three years from us in purchase credits by simply using our products. If you chose to exercise all your credits today, you would have $95,000. Now, since this is a financing program, there is an interest charge on this. The interest charge works this way. In year one, if you only chose to exercise your purchase credits of $27,000 in year one, there'd be no interest charge. If you want to exercise two years' worth of purchase credits, there's a five percent interest charge. Year three there's a 10 percent interest charge — on the total amount of earned purchase credits that you choose to exercise ... Now, here's another thing that you need to think about. The equipment that you asked for — the the (brand name omitted) system, and the argon laser — that comes out to about $60,000. Because we have so much room to work with, that ten percent interest could be paid by

using earned purchase credits. So what I'm telling you is that you could get your (brand name omitted), your argon laser — we've covered the interest charge — and you could get all that with no cash outlay. Does it all make sense to you?

Everything Above Board

Doctor: And you say that this has been reviewed by the lens society — you talking about the American Intraocular Implant Society?
Salesman: Right. HCFA.
Doctor: Medicare and Medicaid looked at it?
Salesman: Yeah.
Second Salesman: I'll show you what the question is — draw you a little picture here so that you'll understand. On the invoice, it'll give a description and let's say it's $375. You only can charge back to Medicare and Medicaid the $325 — you can't take the other $50. There isn't any other company in this point in the game that carves that out. What's happening at other companies ... is the patient is financing the equipment, and that's illegal. There isn't any other company today that has gotten all the endorsement we have. And I think one of the reasons that we get it, as said (name omitted) said earlier, our only game that we play is ophthalmology. If we screw it up, we're in trouble, you're in trouble — it's something that I don't think either one of us wants to be a part of.

Medicare Won't Object to Overcharging

Salesman: Medicare's saying to you, Dr. (name omitted), here's your $504 or your $490 or whatever the reimbursement for facility fee — go out and do whatever you can — that's what we're giving you, so go get your best deal — whether that be a program like this or whatever else.
Second Salesman: Well, the other thing is too, even on the intraocular lenses, if you're aware, at least the way it is around here, it may vary from division of Medicare to divison — they don't look at the invoices. They have a set charge — its' a unit pay charge — whatever they allow and I don't recall right now — $480 or $490 — that they allow. They don't say, well, we won't pay as much because you only paid $300 for that lens. They don't look at that.
Salesman: It's not that way. In some parts of the country where I've been, they pay the invoice price plus 10 percent or something — I don't know why they don't do that here. It's different in every county almost ... programs in Ohio (pay) $625. So it is a little confusing how functionally we would show that breakout. What you do is, you take your — let's say it come to three and a quarter — all of a sudden you put $490 customary charge you know, for handling. As long as that's what they're reimbursing at, you wouldn't have any problems. See, actually, because of the reimbursement scheme we have set up for you, this program is even more ideal for you that it is for other parts of the country, becuase they've already got that price established. And they recognize that as the customary charge on IOLs. So you're in good shape there. But as far as the actual breakdown goes, we go ahead and spell all that out, and it'd be spelled out for you n your invoicing, too. That way Medicare knows exactly what we're doing here.

A Final Seal of Approval

Salesman: The other thing is (name omitted) who is the legal counsel for the society — (name omitted) is also our legal counsel ... So anytime we have any questions of legality, we go directly to (name omitted) on that.
Doctor: That's good to know.

VI. REGULATORY ACTIVITY: IOL ENFORCEMENT, APPROVAL AND REIMBURSEMENT

A. The Food and Drug Administration (FDA)

1. Overview

The Food and Drug Administration is the Federal agency charged with reviewing and approving all intraocular lenses to assure the safety and efficacy of those IOLs to be implanted. While the Subcommittee found no evidence that FDA's fulfillment of and/or its ability to fulfill this charge has led to the release of potentially harmful lenses, it did find inadequacies and laxaties in FDA authority and activities inviting fraud, waste, and abuse in the testing and marketing IOLs.

Until 1976, the FDA's authority to protect consumers from harmful and unreliable medical devices was severely limited. Existing authority was limited to provisions of the 1938 Federal Food, Drug, and Cosmetic Act authorizing action only if a defect was discovered after a product was in use. There was no requirement for premarket approval of medical devices. Moreover, the FDA had to bear the burden of proving the product was in fact dangerous or fraudulent.

On May 28, 1976, Congress enacted the Medical Device Amendments of 1976 (Public Law 94-295). The law was carefully drawn in an attempt to avoid the adverse effects attributed to the role of drug regulation in the United States. Control was imposed only over the industry, not over the medical community, and specific provisions were incorporated to eliminate delays in certain regulatory considerations.

The law requires that the Department of Health and Human Services provide for the classification of medical devices intended for human use based upon their safety and effectiveness as follows:

(1) Class I includes devices not purported to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and do not present a potential unreasonable risk or illness or injury, and for which general controls are sufficient;
(2) Class II includes devices for which it is necessary to establish a performance standard to provide reasonable assurances of their safety and effectiveness; and
(3) Class III devices for which there is insufficient information for the establishment of a performance standard to provide reasonable assurances of their safety and effectiveness, are purported to be for a use which is of substantial inportance in supporting, sustaining, or preventing impairment of human life or health, or present a potential unreasonable risk of illness or injury.

In addition, the legislation:

- Authorizes the Secretary to establish a performance standard for class II devices.
- Requires premarket approval for class III devices and establishes procedures for such approval.
- Places devices intended for human use, which were not placed in interstate commerce before enactment of the amendments, in class III.
- Authorizes the Secretary to ban devices presenting a substantial deception or a substantial risk of illness or human injury under certain circumstances.
- Authorizes the Secretary to notify all persons necessary under the circumstances to eliminate the risk presented by a particular device.
- Authorizes the Secretary to require a manufacturer of a medical device intended for human use which: (1) presents a substantial risk of harm to the public health, and (2) was not properly designed or manufactured, to repair, replace, or refund the purchase price of such device at no cost to the person using it.
- Requires every person who is a manufacturer, importer, or distributor of medical devices intended for human use to establish and maintain whatever records the Secretary may direct by regulation.
- Authorizes the Secretary to establish mandatory manufacturing methods for medical devices.

- Requires the Secretary to provide for public access to information respecting the safety and effectiveness of devices, including information respecting the adverse effects of the device on health.
- Requires manufacturers of medical devices intended for human use to register with the Secretary.
- Provides for an exception from the requirements of this act, under circumstances determined by the Secretary, to permit the investigational use of medical devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

2. IOL Approval Process

Part 813 of Title 21 of the Code of Federal Regulations exempts IOLs from some of the more stringent premarket clearance requirements that other class III devices must meet. In part, this exemption is based on the fact that almost all IOLs are made from same plastic material (PMMA) which has been been adjudged safe and effective for use in the human eye.

The result is that in most instances, all an IOL manufacturer needs to do is file an investigational research protocol with FDA outlining the method to be used to test a particular new lens.

The FDA requires that a manufacturer's investigation produce results of the safety and efficacy of the lens after implantation in at least 500 patients. The data should follow these patients for at least one year and the lenses should be implanted by a qualified investigator (essentially defined as Board Certified Ophthalmologists). This is called a "core" study.

Since these ophthalmologist-investigators are required to document patient progress and produce 6 reports on each patient for manufacturer and FDA use, the FDA does not object to an IOL manufacturer's paying the ophthalmologist for his work as an investigator. The FDA does not regulate the amount paid to investigators.

In addition to the core study, the FDA allows a manufacturer to conduct additional follow-up studies called "adjunct" studies. Adjunct investigators do not routinely have to prepare any reports for FDA use. FDA informed the subcommittee that data maybe available to the manufacturer upon request. FDA also states that FDA does not routinely review this data.

Under this regulatory investigational exemption, manufacturers may arrange for the sale and implantation of the "investigational" IOL by any number of ophthalmologists in any number of patients. The manufacturer may not claim that the IOL is approved or adjudged safe and effective and, at least in theory, all patients receiving the IOL are to to be included in the investigational study. The manufacturer may arrange with any Board Certified Ophthalmologist to be an investigator, and the manufacturer can pay any core or adjunct investigator anything that person wants as compensation for his or her services as an investigator.

3. FDA Backlog and Staffing

The FDA interprets the device legislation to mean that each IOL device produced by each manufacturer, even if identical to another manufacturer approved IOL, must go through the investigational process.

The FDA's Division of Ophthalmic Devices must approve each IOL, contact lens, contact lens saline solution, laser, and surgical device. The Division has a staff of 35 as of May 31, 1985 and has a pending backlog of 896 IOLs in preinvestigational and investigational stages awaiting final approval. As of June 1, 1985, the FDA had approved a total of 76 IOLs. Before the first IOL was finally approved by the FDA, over 500,000 "investigational" IOLs had been implanted in patients' eyes. In April 1985, the FDA has just approved the first IOL in over a year because the staff was diverted to reviewing other ophthalmic devices.

4. Misuse of FDA Approval Process

Subcommittee staff has been made aware of the fact that numerous abuses of the FDA process exist. Several manufacturers have used the IOL investigational process as a way to avoid the anti-kickback and fraud laws. The manufacturers are in effect, paying bribes to ophthalmologists to use a specific lens by calling the bribe a payment for the doctor's services as an investigator. This is especially prevalent in adjunct studies which really do not place any additional work or reporting burden on the physician. Most manufacturers interviewed by Subcommittee staff acknowledged the existence of this problem and decried the absence of any enforceable industry standards.

FDA has issued warning letters to manufacturers for problems related to investigational implants in large numbers of patients, but no further enforcement action was adjudged necessary by FDA. Despite the abuses of the adjunct investigational process, FDA stated that it "currently has the necessary authority to control adjunct studies."

In May of 1985, the Chairman mailed a questionnaire to the Commissioner of the Food and Drug Administration. The questionnaire focused on the FDA's policies and activities related to the approval of IOLs. The questionnaire and the FDA's response can be found in Appendix C of this report.

B. The Office of the Inspector General

1. Overview

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) was established by Congress in 1976. Congress intended that the OIG be independent of the program operations of the department and that the Inspector General could report only to the Secretary of HHS or to the Congress. This was to assure that the OIG would have the appropriate staffing and flexibility to combat fraud, waste and abuse within the department and the programs (including Medicare) which it administers.

At the request of Chairman Pepper and the Subcommittee, an audit and a preliminary inspection were completed by OIG to review practices in billing and paying for cataract surgery through the Medicare program. The OIG staff reviewed a statistically valid sample of hospital and ophthalmologist bills to Medicare for cataract surgery. Their investigation uncovered program waste and a considerable amount of fraud.

2. Lens Manufacturer Practices

The Inspector General investigation confirmed for the Subcommittee its own evidence of a number of illegal practices involving the sale of intraocular lenses (IOLs). The Inspector General concluded that "the circumstance that gives rise to these ripoffs is the excessive Medicare payments for the lenses." The IG found that the IOL manufacturers were extraordinarily profitable and that much of the illegal activity in can be attributed to some of their overly aggressive salesmen. The Inspector General found that some of the lenses cost as little as $35 to manufacture. A profit of $150 or more is not uncommon on some of these lenses.

3. Provider Charges for IOLs

The OIG review found that provider mark-up for IOLs could even be higher than that of the manufacturers. Lenses that may cost a provider $150-$250 were found to have been charged to Medicare at prices from $300 to over $700. Thus, provider mark-ups ranged from $50 to $550.

As stated earlier, when cataract surgery covered by Medicare is performed on an outpatient basis, the Medicare patient must pay 20 percent of the provider's IOL cost. The OIG investigation uncovered instances where the mark-up was so high that the patient's 20 percent payment was more than the provider's original cost for the lens.

The OIG study did not find any relationship between what Medicare was billed and paid for, and providers' original costs for IOLs.

Charges were even more astonishing when ophthalmologists rather than hospitals were billing Medicare for IOLs. The range of prices paid by doctors were from $0 to $425. The Inspector General found a well known physician who received 1600 free IOLs in exchange for the use of his name in marketing the lense. He billed Medicare $500 for each of these "free" lenses. Last year he made $80,000 profit just on lenses — $65,000 was paid by Medicare and $15,000 by his patients. Including surgical fees, this doctor received over $1.3 million from the Medicare program.

The Inspector General concluded that, "Since the Medicare program is willing to pay 200 percent to 500 percent of the provider's cost for these lenses, it is not surprising that ripoff schemes are prevalent."

Based on a statistically valid sample, OIG found that last year alone, Medicare paid ophthalmologists $6.5 million more that their IOL costs, and beneficiaries paid them an additional $2.8 million. Based on a review of hospital costs and charges, OIG estimates that overall $50 million was wasted by Medicare last year just for IOLs.

4. Excessive Physician Fees

In addition to the problems of IOL costs, the Inspector General's investigation revealed other problems related to cataract surgery paid for by Medicare.

Medicare pays separate bills for cataract surgery to the surgeon, the anesthesiologist, and sometimes an assistant surgeon. The fee Medicare pays for the surgeon's services was determined before the technological changes and advances in skill made cataract surgery less time consuming and complicated. Medicare pays between $960 and $2,000 to the surgeon for an operation usually performed in 30 minutes. Many ophthalmologists were paid more than $1 million by Medicare in 1984 for cataract surgery. One Florida surgeon performed over 5,000 surgeries in 1984 and received $6.4 million in reimbursement. In the state of Texas alone, six ophthalmologists were paid over $1 million by Medicare in one year.

The OIG study corroborates one of this Subcommittee's most frequent findings: Medicare's reimbursement methods are unable to keep up with technological changes which can substantially lower charges as well as raise them.

In addition, an OIG audit finds little or no justification for Medicare reimbursement for an assistant surgeon in the performance of cataract surgery. These duties are just as competently performed by a nurse or other skilled personnel. The Inspector General estimates that eliminating these payments could save Medicare between $150-$200 million over a five-year period.

Over 90% of cataract surgeries now involve a local anesthetic—frequently administered by the surgeon. Medicare nevertheless pays the same amount ($120-$350) to the anesthesiologist (if one was present during the operation), if he or she used general anesthetic. The Inspector General questions the necessity for Medicare anesthesiologist payment for any but the most complicated cataract surgeries. At the least, Medicare reimbursement should reflect differences in depending whether general or local anesthetic was used and whether the anesthesiologist merely was on "stand-by" for the surgery.

C. Health Care Financing Administration (HCFA)

The Health Care Financing Administration (HCFA) within the Department of Health and Human Services is the Federal agency responsible for the administration and oversight of government reimbursement for cataract surgery through the Medicare program. The Subcommittee found serious inadequacies in HCFA's oversight and policy in this area resulting in the waste of over $1.2 billion in Medicare funds.

The Medicare program, which began on July 1, 1966, was authorized by the Social Security Amendments of 1965, which added Title XVIII of the Social Security Act. Medicare pays for much of the health care costs for eligible persons aged 65 or older. The program is administered by the Health Care Financing Administration (HCFA), a component of the Department of Health and Human Services (HHS).

HCFA administers Medicare through a network of contractors, such as Blue Cross and Blue Shield, to process Medicare claims and to make payments on behalf of the government. The contractors that pay institutional providers, such as hospitals and nursing homes, are referred to as part A intermediaries; the contractors that pay for the services of noninstitutional providers, such as doctors, laboratories, and suppliers, are called part B carriers.

In fiscal year 1984, Medicare paid about $42 billion to the approximately 6,000 hospitals that participate in the program. We estimate that expenditures for inpatient and outpatient services for cataract surgery under Medicare in fiscal year 1985 will amount to about $3.5 billion.

From Medicare's initiation on July 1, 1966, until fiscal year 1984, the program paid hospitals, on a retrospective basis, their reasonable costs of providing covered services to beneficiaries. Although the reasonable cost methodology included provisions designed to control Medicare cost growth, there was a general concern that this payment system did not give hospitals sufficient incentives to provide care economically and efficiently. As a result of this concern, the Congress enacted as part of the Social Security Amendments of 1983 (Public Law 98-21) a hospital prospective payment system for Medicare. Under the new system, the amount a hospital will be paid is determined before the period in which the payments are made, and normally payments are not adjusted retrospectively to reflect actual costs. The payment rate depends on into which diagnosis related group (DRG) the case is classified. The prospective payment system is being phased in over 3 years beginning in fiscal year 1984, and eventually hospitals will be paid a uniform rate (adjusted to reflect variations in local wage levels, urban or rural location, and teaching status) established for each DRG.

Each DRG contains diagnoses which are expected to be closely related in the extent of resources devoted to treating patients. DRG 39, Lens Procedures, which includes the removal of cataracts, resulted in over 395,000 discharges during fiscal year 1984. In addition, DRG 42, Intraocular Procedures except Retina, Iris and Lens, which was intended to cover complications of cataract and other eye operations, resulted in almost 35,000 discharges. HCFA was unable to provide us with accurate data on the number of non-DRG inpatient cataract operation performed in 1984.

The Social Security Amendments of 1983 also strengthened the role of utilization and quality control Peer Review Organizations (PROs), which are usually statewide bodies of medical professionals under contract with HCFA to review the medical necessity and appropriateness of health care services provided under Medicare. The amendments require hospitals, as a condition of receiving Medicare payments, to enter into a contract with the PRO covering their area, to review such factors as quality of care and utilization of services. The legislation also specifies that PROs will review the validity of diagnostic information provided by hospitals and the appropriateness of admissions and discharges. HCFA required most PROs to review every inpatient cataract surgery procedure and to deny payment for all that are unnecessary. The primary focus of the PROs however is to ensure that no cataract surgery be performed inpatient if it can be performed outpatient instead. The assumption behind this policy is that outpatient surgery is less expensive, and less traumatic for the patient.

Despite the fact that HCFA is rapidly forcing most cataract surgery from inpatient to outpatient, we have been informed that "Data on procedures for outpatient hospital services are not collected." No data was provided for other outpatient locales.

Hence, HCFA in effect has no practical way to evaluate the effectiveness (or ineffectiveness) of the policy they are implementing.

As discussed in Section I B(1) of this report, HCFA has no uniform policy requiring its carriers and intermediaries to cap reimbursement for IOLs. This allows for great variations found by the Subcommittee in rates from $290-$665 paid by Medicare for essentially identical lenses.

In May of 1985, the Chairman mailed a questionnaire to the Administrator of the Health Care Financing Administration. In his request for information, the Chairman posed a series of questions relating to HCFA's policies and activities surrounding Medicare payments associated with cataract surgery. The questionnaire and HCFA's response can be found in Appendix D of this report.

VII. POLICY RECOMMENDATIONS

It is apparent that cataract surgery represents the best and worst of modern medicine. The Subcommittee is impressed with the technological advances made in the last five years. Cataract surgery is now faster, less painful and more effective. For literally millions of senior citizens these improvements have provided the precious gift of better vision.

From the taxpayers' perspective, however, cataract surgery is an unmitigated disaster. With almost 50 percent of all the money spent on cataract surgery drained away by fraud, waste and abuse, Americans are losing up to $2 billion annually. If nothing is done, upwards of $12 billion, $10 billion by the Medicare program alone, will be lost by the end of this decade.

At a moment in time when Congress is struggling to find ways to reduce the soaring Federal deficit, often by making difficult and painful program reductions, we cannot in good conscience ignore this grand scale squandering surrounding cataract surgery.

With some improvements in program administration and legislative changes, we could continue to provide necessary and effective cataract surgery, enjoy its rich benefits, but without the fraud, waste and abuse. During the course of its investigation the Subcommitee has developed a series of recommendations — to the Congress, Federal agencies, senior citizen consumers and others — aimed at providing these much needed improvements.

— Congress should consider legislation which would limit Medicare payments for cataract surgery performed in a hospital outpatient or ambulatory surgical center setting to some percent less than that paid for the same in a hospital inpatient setting. Information on cost savings, program effectiveness and patient well-being derived from this change could serve as a basis for adopting this policy for all surgicel procedures performed in different settings.

— Congress should consider legislation eliminating Medicare payments for asssistant surgeons for all outpatient surgery unless preapproved by the PRO or Medicare carrier.

— Congress should consider legislation requiring HCFA to set strict policy and reimbursement limits on anethesiologist bills— paying only for general anesthesia anod only if preapproved. Medicare should only pay a nominal amount if an anesthesiologist is only on "stand by".

— Congress should consider legislation requiring Medicare to pay cost and not charges for all prosthetic devices.

— Congress should consider legislation giving FDA authority to regulate amounts paid by manufacturers to investigators of all types of investigational devices.

— Congress should consider legislation to require the Congressional Office of Technology Assessment (OTA) to conduct an annual review of changes in technology and skill involving artificial devices and organs and their implantation and to advise the Secretary of DHHS to reflect changes in Medicare charges.

— One distressing finding of the Subcommittee is that from 23%-36% of all cataract surgery may be unnecessary. Instances of senior citizens with perfect 20/20 vision being operated on were reported. We therefore strongly recommend that anyone needing cataract surgery seek the opinion of at least one other qualified doctor before undergoing surgery. Unnecessary surgery is not only wasteful but can adversely impact on the patient's health and well-being.

Health Care Financing Administration (HCFA)

The Subcommittee is dismayed that HCFA is busy implementing a policy of forcing all cataract surgery from inpatient to outpatient basis, without collecting any data to allow it to evaluate how this policy is working. We are distressed that HCFA has not made any effective effort to control the excessive charges made by hospital outpatient departments, or for unnecessary professional services in all surgical procedures.

— HCFA should immediately begin to collect and analyze data on all outpatient surgeries reimbursed for by Medicare to determine their costs and effectiveness.

- HCFA should immediately implement and enforce a uniform policy for its carriers on payments for IOLs.

Food and Drug Administration

The Subcommittee is distressed that FDA has allowed the continuation of adjunct studies of IOLs. We see these studies as wasteful and of little if any use. FDA does not use the data collected from these studies. Many of these studies are required of IOLs which are identical to those already approved for use.

The Subcommittee is also distressed that FDA has scant little control over who conducts investigations of nonapproved devices, what these investigators are paid by the manufacturers of these devices, and the extent of commercialization of nonapproved devices.

- The FDA should immediately take steps to eliminate adjunct studies for IOLs.

- The FDA should take steps to reduce its backlog of devices awaiting approval.

U.S. Department of Justice

The Department of Justice should actively seek out and prosecute cases of fraud and abuse involving cataract surgery and the sale of IOLs.

Ophthalmology Profession

The professional associations should formally censure the types of improper and illegal sales inducements outlined in this report.

VIII. CONCLUSION

The Subcommittee found that cataract surgery — the most frequently reimbursed major surgical procedure under the Medicare program — is fraught with fraud, waste and abuse. As this report has shown, there is reason to question the necessity or validity of half of the dollars that Medicare pays for cataract surgery — as much as $2 billion of the $3.5 billion we pay for this miraculous procudure is drained away inappropriately.

At a moment in time when Congress is struggling to find ways to reduce the soaring Federal deficit and retain important income and health benefits for senior citizens, often by making difficult and painful program reductions, we connot in good conscience ignore this grand scale squandering surrounding cataract surgery.

With some improvements in program administration and legislative changes, we could continue to provide necessary and effective cataract surgery, enjoy its rich benefits, but without the fraud, waste and abuse.

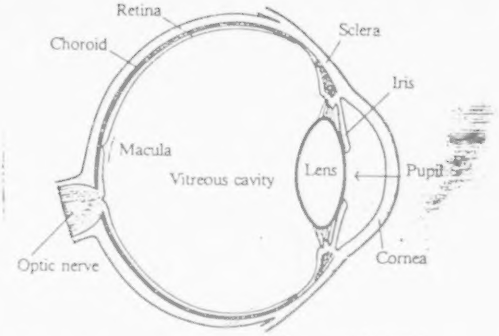
It is our hope that this report will lead to much needed reform and that the millions of Americans who will be seeking this surgery will get the most appropriate and affordable care available.

IX. GLOSSARY OF TERMS SPECIFIC TO THE CATARACT INDUSTRY AND AN ANATOMY OF THE EYE

Glossary of Terms:

aphakia:	the absence of the natural lens of the eye, most commonly the result of cataract surgery.
ASC or Ambulatory Surgical Centers:	operating rooms located outside of hospitals in which outpatient surgery is performed.
cataract:	a cloudy or opaque area in part or all of the transparent lens located inside the eye.
cryoextraction:	an intraocular extraction technique by which a cataract is frozen and removed using a very cold probe.
DRG or Diagnostic Related Group:	one of 468 categories for disease and disorders upon which Medicare part A bases its reimbursement schedules.
extracapsular extraction:	method of cataract removal in which the clouded lens is removed along with the front portion of the lens capusle, while the rear portion of the capsule is left behind.
Healon (Sodium Hyaluronate):	a thick, gel-like, man-made material injected into the eye to maintain its shape during surgery.
intracapsular extraction:	method of cataract removal in which the entire lens capsule is removed along with the clouded lens.
IOL or intraocular lens:	a synthetic lens inplanted in the eye used to replace the natural crystalline lens.
prosthetic lenses:	lenses which work in conjunction with or replace the natural lens of the eye, including glasses, contact lenses, and IOLs.
vitreous humor:	a very thick, gel-like natural material found in the eye that serves to maintain the spherica shape of the eye.

An Anatomy of the Eye



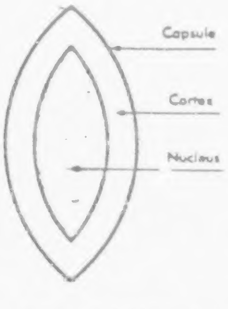
Cornea: the clear membrane covering the exterior surface of the eye. It is reponsible for focusing the light rays on the retina, and is misshapen in conditions such as astigmatism, nearsightedness,and farsightedness. These conditions are usually corrected by glasses or contact lenses.

Iris: the colored portion of the eye which forms a ring around the pupil.

Pupil: the aperature which permits light to enter the eye. The diameter is varied to alter the amount of light permitted to enter depending on the brightness of the environment.

Sclera: the white of the eye.

Lens: the lens functions to allow the eye to change its focus between near and far objects.



crystalline lens

Vitreous cavity: the large chamber behind the lens, filled with vitreous humor, a very thick gel-like fluid which maintains the shape of the hollow eye.

Retina: sensory sight of the eye where light input is transformed into electrical neural input so that it can be interpreted by the brain.

Macula: the area of the retina containing the highest density of rods and cones, the specialized cells which transform light into neural information. The macula is reponsible for fine discriminative vision.

Choroid: the portion of the eye containing the blood vessels which supply the retina.

Optic nerve: the nerve which transmits the visual input from the eye to the brain.

7. If you participate in a purchase arrangement which provides a financial incentive or benefit for dealing with a particular company, do you pass along the savings to your patients and any affected third party payor?______YES ______NO If yes, please explain how you pass these savings along to the Medicare program or beneficiary/patient.

7a. How much financial benefit is derived from this plan?______________________________

8. Do you feel that intraocular lens manufacturers/sales representatives should be free to offer incentives to physicians to purchase a particular brands of lens? ____Yes ____No Why? ______________________________

9. Would you be willing to testify before this Subcommittee on your experience and/or knowledge of intraocular lens purchase arrangements? ____Yes ____No

11. Please feel free to share any additional thoughts you may have on attached sheets or call us at (202) 226-3381 with this information.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO:

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
Select Committee on Aging
H2-377
U.S. House of Representatives
Washington, DC 20515

Thank you in advance for your prompt response.

APPENDIX A

OPHTHALMOLOGIST QUESTIONNAIRE

NAME: ____________________

ADDRESS: ____________________

____

____

____

TELEPHONE: ____________________

1a. How many patients did you see/treat in 1984?____ In 1983?____
1b. What percentage of your patients are over the age of 65?____%

2a. With which intraocular lens manufacturer do you do business?

____

2b. Are you an investigator for this manufacturer?____YES ____NO

3. Are you aware of any of the following types of purchasing arrangements which may be employed by intraocular lens manufacturers/sales representatives?

		YES	NO
a.	Awards of vacations to physicians for purchasing a certain number of intraocular lenses	____	____
b.	Discounts to physicians for volume purchases of intraocular lenses	____	____
c.	Gifts of stock in your company to physicians who purchase a certain number of lenses	____	____
d.	Cash rebates to physicians who purchase from your company	____	____
e.	Free intraocular lenses provided to physicians after they have purchased a certain number from your company	____	____
f.	Progressive discounts for repeat volume orders	____	____

g. Other (please specify) ____________________

____

____

____

Please describe any other purchase arrangements you are aware of. Also, please use this space to elaborate on any "Yes" answers above.

4a. Are these arrangements being offered by the manufacturers or manufacturer salesmen with whom you do business? ____YES ____NO
4b. To your knowledge, are these arrangements being offered by other manufacturers? ____YES ____NO If yes, by whom?

5. Do you consider these arrangements to be kickbacks, bribes or other improper inducements?____YES ____NO Elaborate, if necessary.

6. Have you ever declined to participate in a purchase arrangement similar to those described above, or others?____YES ____NO If yes, why?

APPENDIX B

INDUSTRY QUESTIONNAIRE

(Please attach additional sheets if needed)

Name of Firm:
Address:

Contact Person:
Telephone:

1. In how many states do you operate? ______

2. What were you total assets in 1983? ______ In 1984? ______

3. What were your total gross revenues from sale of intraocular lenses for 1983? ______ 1984? ______

   Could you please furnish us a copy of your most recent annual report?

4. How many people does your company employ? ______ How many are involved in marketing your intraocular lenses? __________ Of these, how many are sales representatives? __________ How many are administrative? __________ Other? provide a distribution by state.

5. Are your sales representatives your employees or are they independent contractors? Employees ___% Independent Contractors ___% Others (specify) ___%

6. Do you provide company training relative to intraocular lens sales to your sales representatives? ___YES ___NO. If yes, could you please provide me with a copy of your training manual.

   Is it mandatory to undertake this training before selling your lenses?
   ___YES ___NO If not, why not?

7. Do your sales representatives work on a salary basis ____%, commission basis %, or combination of the two? ___%

8. What is the average yearly income (excluding benefits) for your intraocular lens sales representatives? ______________

9. Are you aware of intraocular lenses being marketed under any of the following sales plans?

	YES	NO
a. Awards of vacations to physicians for purchasing a certain number of intraocular lenses		
b. Discounts to physicians for volume purchases of intraocular lenses		
c. Gifts of stock in your company to physicians who purchase a certain number of lenses		
d. Cash rebates to physicians who purchase from your company		
e. Free intraocular lenses provided to physicians after they have purchased a certain number from your company		
f. Increasingly greater discounts to physicians who make repeated volume orders.		
g. Other (specify)		

Please attach sheet to elaborate on any "Yes" answers above.

10. Have you or your sales representatives ever employed these techniques? Please describe any other marketing plans your company employes. Also, please use this space to elaborate on any "Yes" answers.

Are these company plans or are they employed on an optional basis by individual sales representatives? If so, which ones?

11. If your company does not employ any marketing plans similar to those above, are you, nevertheless, aware of any companies which utilize such plans?
___YES ___NO
Please identify the companies and/or nature of their marketing plans.

12. What is the purpose of employing these marketing techniques?

13. If your company employs a marketing plan which offers a financial incentive or benefit to participating physicians, do you advise them to pass along their benefit in terms of cost savings to the patients and third party payors?____Yes _____No

If not, why not?

If yes, how do physicians pass along savings under your plan?

14. Have your representatives ever been approached by physicians asking for special considerations, money or other inducements for using your lens?____Yes ____No
If so, please explain.

15. How would you characterize the nature of the industry?____Competitive
____Non-Competitive ____Very competitive

16. Would you be willing to testify before this Subcommittee on the marketing of intraocular lenses? _____Yes _____No

17. Please feel free to share any additional comments you may have on attached sheets, or call us at (202) 226-3381 with this information. Thank you for responding.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO:
Subcommittee on Health and Long-Term Care
House Select Committee on Aging
H2-377
U.S. House of Representatives
Washington, DC 20515

APPENDIX C

[illegible]
[illegible]
[illegible]
THOMAS A. LUKEN, OHIO
DAN MICA, FLORIDA
HENRY A. WAXMAN, CALIFORNIA
MIKE SYNAR, OKLAHOMA
BUTLER DERRICK, SOUTH CAROLINA
BRUCE F. VENTO, MINNESOTA
BARNEY FRANK, MASSACHUSETTS
RON WYDEN, OREGON
IKE SKELTON, MISSOURI
DENNIS M. HERTEL, MICHIGAN
ROBERT A. BORSKI, PENNSYLVANIA
BEN ERDREICH, ALABAMA
BUDDY MacKAY, FLORIDA
NORMAN SISISKY, VIRGINIA
EDWARD R. ROYBAL, CALIFORNIA (EX OFFICIO)

KATHLEEN GARDNER CRAVEDI
STAFF DIRECTOR

MELANIE MODLIN
ASSISTANT STAFF DIRECTOR

PETER REINECKE
DIRECTOR OF RESEARCH

JAY CONSTANTINE
BILL HALAMANDARIS
LEWIS H. KULLER, M.D., D.P.H.
CONSULTANTS

(202) 226-3381

U.S. House of Representatives
SELECT COMMITTEE ON AGING
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
377 HOUSE OFFICE BUILDING ANNEX 2
Washington, DC 20515

[illegible]
JIM COURTER, NEW JERSEY
CLAUDINE SCHNEIDER, RHODE ISLAND
THOMAS J. RIDGE, PENNSYLVANIA
JOHN McCAIN, ARIZONA
SHERWOOD L. BOEHLERT, NEW YORK
JIM LIGHTFOOT, IOWA
JAN MEYERS, KANSAS
PATRICK L. SWINDALL, GEORGIA
PAUL B. HENRY, MICHIGAN
JIM KOLBE, ARIZONA
MATTHEW J. RINALDO, NEW JERSEY (EX OFFICIO)

MARK BENEDICT, J.D.
MINORITY STAFF DIRECTOR

LORI LIGHTFOOT
ASSISTANT STAFF DIRECTOR

(202) 226-3383

May 22, 1985

Dear Dr. Young:

The Subcommittee on Health and Long-Term Care of the House Select Committee on Aging is investigating a number of issues involving cataract surgery. To this end, we would very much appreciate your agency providing us with the following information:

- o How many interocular lenses (IOL's) have received final FDA approval?
- o How many IOL's are approved for core investigational study?
- o How many IOL's are approved for adjunct studies?
- o How many IOL's are awaiting approval to begin investigational studies?
- o What is the current staffing of the Division of Opthalmic Devices and what is the overall pending workload?
- o What specific steps has FDA taken to prohibit overcommercialization of univestigated IOL's?
- o Has FDA investigated or taken any compliance actions against any IOL manufacturers? To what use does FDA put adjunct studies? Should FDA's authority to control adjunct studies be changed in any manner?
- o FDA's authority to regulate devices is almost ten years old. In light of your experience in this area, are there some legislative or regulatory mandates which should be changed either to simplify procedures or to strengthen regulatory authority?

We would like to ask that we receive this important information by June 3, 1985. If you or your staff has any questions regarding this request, please contact the Subcommittee Staff Director, Kathleen Gardner Cravedi, at (202)226-3201.

Kindest regards, and,

Very sincerely,

Claude Pepper

Claude Pepper
Chairman

Frank E. Young, M.D., Ph.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

CP:pgr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 03 1985

The Honorable Claude Pepper
Chairman, Subcommittee on Health
and Long-Term Care
Select Committee on Aging
House of Representatives
Washington, D.C. 20515

Dear Mr. Pepper:

I write to reply to your letter dated May 22, 1985 regarding the Food and Drug Administration's intraocular lens (IOL) activities. I am pleased to submit the enclosed information which details the Agency's activities, both in terms of processing applications for new investigational products as well as enforcement of the present rules and statutory requirements.

Enclosed is material responsive to your questions on the Agency's IOL program. I will be happy to provide any additional information you may want on this important issue.

Sincerely yours,

Frank E. Young

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure

RESPONSE TO MR. PEPPER'S REQUEST FOR INFORMATION ON INTRAOCULAR LENSES

Responses to questions raised in Mr. Pepper's letter are provided in the order in which the questions appeared in the May 22, 1985, letter. The intraocular lens (IOL) utilization data provided in items 1 through 4 are based upon data obtained from a telephone survey conducted during the week of May 30 through June 3, 1985, of 18 IOL manufacturers that are operating under approved investigational device exemption (IDE) applications. Although FDA has not verified the accuracy of each and every number provided by the manufacturers, we have no reason to doubt their accuracy.

1. Question: How many IOLs have received final FDA approval?

   Response: As of May 31, 1985, premarket approval applications (PMAs) had been approved for 7 different manufacturers to market 76 different IOL models. These 76 models include 59 posterior chamber IOLs by 6 different manufacturers, 11 anterior chamber IOLs by 4 manufacturers, 4 iridocapsular IOL models by 2 manufacturers, and 2 iris fixation IOL models by 1 manufacturer.

   During the period of January 1, 1984, through December 31, 1984 (in some instances February 1, 1984, through January 31, 1985), approximately 103,043 PMA approved IOLs were implanted.

2. Question: How many IOLs are approved for core investigational studies?

   Response: As of May 31, 1985, 313 different IOL models had been approved for core investigational studies for 16 different manufacturers. During the period identified in the second paragraph of the response to item 1, approximately 23,497 core investigational lenses were implanted. The models include 164 IOL models made of standard polymethylmethacrylate (PMMA), 135 models made of PMMA plus UV-absorbing materials, and 14 models made of soft materials.

3. Question: How many IOLs are approved for adjunct studies?

   Response: As of May 31, 1985, 531 different IOL models had been approved for adjunct studies by 17 manufacturers. During the period identified in items 1 and 2, approximately 714,286 adjunct investigational IOLs were implanted. The models included 346 models made of standard PMMA and 185 models made of PMMA plus UV-absorbing materials.

4. Question: How many IOLs are awaiting approval to begin investigational studies?

   Response: As of May 31, 1985, 52 different IOL models are awaiting approval to begin investigational studies (i.e., the IDE applications have been at FDA for fewer than 30 days). These models include 7 IOLs made of standard PMMA, 44 IOLs made of PMMA plus UV-absorbing materials and 1 IOL made of soft material.

5. Question: What is the current staffing of the Division of Ophthalmic Devices (DOD), and what is the overall pending workload?

Response: DOD is the largest of seven divisions in FDA's Center for Devices and Radiological Health (CDRH) Office of Device Evaluation (ODE), with 35 full-time equivalents (FTEs) currently on board. Twenty-five percent of ODE's scientific review personnel are allocated to DOD. To compensate for growing workloads, staffing of DOD has been increased by 5.5 FTEs since the beginning of Fiscal Year (FY) 1985, despite a reduction in overall resources in FDA's CDRH.

DOD has three branches: the Intraocular Lens Branch, the Contact Lens Branch, and the Surgical and Diagnostic Devices Branch.

During the first half of FY 1985, the incoming workload of DOD was as follows:

Type of Submission	No. Received by DOD	DOD's Share of Total ODE Submissions
Premarket Notifications (510(k)s)	98	4%
IDE Applications	26	28%
IDE Supplements	463	36%
PMAs	23	52%
PMA Supplements	89	45%
Total	699	17%

*DOD's share of total ODE workload (number of incoming submissions weighted by resource-intensiveness) equals 27%.

Currently, the following numbers of submissions are under active review in DOD:

Type of Submission	No. Under Review	DOD's Average Response Time (Days) Per Submission, First Half FY '85
Premarket Notifications (510(k)s)	26	94
IDE Applications	9	55
IDE Supplements	750	34
PMAs	42	356*
PMA Supplements	228	287*

---

*PMA review times are for "initial" decision -- the first decision on the approvability of the application after it has been accepted for filing — excluding time for manufacturer's responses to scientific deficiency letters.

6. Question: What specific steps has FDA taken to prohibit over-commercialization of uninvestigated IOLs?

Response: We are not certain what you mean by uninvestigated IOLs. Therefore, we are directing our response to the steps which FDA has taken to prevent the commercialization of investigational IOLs and those IOLs that FDA has not approved.

The IDE regulation for IOLs (21 CFR Part 813) allows sponsors to charge for an IOL, provided the sponsor, in the IDE application, notifies FDA that there will be a charge to investigators and subjects for the device (813.20(b)(15)). No further information regarding charges is generally submitted or requested.

Other steps that FDA has taken to limit the commercialization of investigational IOLs include limits on the promotional practices and advertising by sponsors and investigators. Regulation 21 CFR 813.50 prohibits the sponsor or any person acting for or on behalf of the sponsor to disseminate any promotional material that represents that the lens being investigated is safe and effective for the purposes for which it is being investigated. Such claims are also prohibited in advertising and in the representations made at trade shows or professional conferences. Such claims would provide cause for withdrawal of approval of IDE or other regulatory action. FDA has developed a "Guideline for Reviewing Notices of Availability for Intraocular Lenses" (enclosure 1) which has been widely distributed throughout the IOL industry. This guideline outlines information that would be acceptable to FDA in notices of availability of IOLs.

Please refer to enclosure 2 in reply to Question 7a (section 813.50, pages 4-5) for a summary of actions taken by FDA against firms that promoted the use of their IOLs during their investigation.

7a. Question: Has FDA investigated or taken any compliance actions against any IOL manufacturers?

Response: FDA's regulatory actions regarding IOL investigations are summarized in enclosure 2. These actions were based on violations of the IOL regulation (21 CFR 813) and on reviews of IDE applications submitted in accordance with the IOL regulation.

7b. Question: To what use does FDA put adjunct studies?

Response: FDA requires that data from these studies be available to the sponsor upon request.

Adjunct visual acuity and complication rate data have been used to confirm core data although these data are not routinely reviewed in PMAs.

Under section 813.153 of FDA's regulations, if during an investigation a serious adverse reaction occurs that may reasonably be regarded as lens related and that was not anticipated in nature, severity, or degree of incidence in the investigational plan (adverse reactions include any incidence of hypopyon, intraocular infection, acute corneal decompensation--or any secondary surgical intervention), the investigator must investigate the reaction and submit an accurate and adequate report of the investigation to the sponsor within 5 days. The sponsor in turn must report the adverse reaction and results to FDA within 5 days. All adverse reactions (core and adjunct) are analyzed by the sponsor and FDA for PMA approval purposes.

7c. Question: Should FDA's authority to control adjunct studies be changed in any manner?

Response: No. FDA currently has the necessary authority to control adjunct studies. The Investigational Device Exemption Criticism Task Force recently considered this question and concluded that additional authority to control adjunct studies is not necessary. How adjunct studies (which are not specifically mentioned in 21 CFR, Part 813) are controlled is a matter of FDA policy and interpretation of the regulations.

As you know, when FDA initially began regulating IOLs under the Medical Device Amendments of 1976, while Congress was considering these Amendments, some ophthalmologists expressed concern that the new law would unduly inhibit the development of IOLs; IOLs were on the market at that time. Therefore, Congress directed FDA to ensure that IOLs continue to be made "reasonably available" to qualified investigators to implant while data were being collected that would enable FDA to decide whether IOLs should be approved for general marketing. The adjunct study was designed to fulfill that purpose and to collect data on infrequently-occurring complications.

At this time FDA believes that because a large number of IOL models have been granted PMA approval and PMA approval is imminent for several other models, the Congressional mandate of assuring that IOLs be made "reasonably available" has been met. For this reason, FDA is reexamining its policy of allowing sponsors to include adjunct study patients in their investigational protocols. FDA is developing a policy on (a) whether investigations of new IOLs should be restricted to core patients; (b) whether and how additional patients may be entered after submission of a PMA to FDA; and (c) what should be done about ongoing investigations that include adjunct studies.

8. Question: FDA's authority to regulate devices is almost ten years old. In light of your experience in this area, are there some legislative or regulatory mandates which should be changed either to simplify procedures or to strengthen regulatory authority?

Response: On April 23, 1985 Secretary Heckler submitted to Congress a legislative proposal that would simplify the medical device standard-setting process (i.e., streamlining the current five-step process into a two-step process) and would provide discretionary authority for the initiation of such standards. That proposal has been introduced as H.R. 2177.

In addition, FDA has recently undertaken an intensive review of the Medical Device Program. This review resulted in the establishment of 11 task forces to review the following areas: civil penalties, device definition, education, good manufacturing practices, investigational device exemption, premarket approval, preamendment PMA, premarket notification, reclassification, 518(b) and the effect of the Medical Device Amendments on small business.

These task forces have completed their deliberations and are in the process of finalizing reports that may contain recommendations for changes in management processes, policy, regulations, and the statute.

Enclosure 1

GUIDELINE FOR REVIEWING NOTICES OF AVAILABILITY FOR INTRAOCULAR LENSES

a. be limited to information needed to adequately inform physicians of their availability for investigational use;

b. be placed only in medical or scientific publications whose readership is composed of physicians or institutions providing ophthalmological services;

c. not include claims, either overt or implied, that the lenses are safe or effective for the purposes under investigation;

d. include only objective statements concerning the physical nature of the lenses; i.e., size, power, composition, etc.;

e. not include comparative pictorial descriptions, but may include reasonably sized drawings or photographs of the lenses;

f. include the following statements, prominently displayed in type consistent with other type in the notice;

"Caution - investigational device. Limited by Federal (or United States) law to investigational use."

g. include the name and address of the sponsor and may include statements describing how they can be obtained.

In the future our staff will use the above for guidance when reviewing material for possible violations of 21 CFR 813.50.

Division of Compliance Operations
May 1981

Enclosure 2

INTRAOCULAR LENSES (IOLs)

Section 813.25(a):

1. On 11/2/82, Precision Cosmet was issued a letter regarding the high rate of macular edema with the lenses implanted. No further regulatory action was necessary since appropriate steps were taken by the sponsor to correct the problem.
2. On 6/8/81, Precision Cosmet was issued a letter regarding the carcinogenic effects of the blue suture material and requested further study. No further regulatory action was necessary since the sponsor resolved the issue.
3. On 11/14/79, Precision Cosmet was issued a letter regarding the incidence of adverse effects in anterior chamber lenses and that further addition of investigators will be denied. No further regulatory action was necessary since the sponsor resolved the issue.
4. On 5/27/83, Copeland Intra Lenses was issued a letter regarding the safety issues associated with the ICCE implantation portion of the protocol. No further regulatory action was necessary since the sponsor voluntarily terminated that portion of the investigation.
5. On 9/9/82, Intermedics was issued a letter regarding the incidence of adverse effects with the iris plane lenses. No further regulatory action was necessary since the sponsor voluntarily ceased further implantation.
6. On 9/16/83, Intermedics was issued a letter regarding the high rate of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.
7. On 11/1/82, Surgidev was issued a letter regarding the high rate of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.
8. On 7/14/83, Medical Workshops was issued a letter regarding the problem of low visual acuity with the Medallion IOLs. No further regulatory action was necessary since the sponsor resolved the issue.
9. On 9/14/81, Medical Workshops was issued a letter regarding the incidence of adverse effects. No further regulatory action was necessary since the sponsor resolved the issue.

Section 813.39(b):

1. On 7/12/78, Coburn Optical Industries was issued a letter regarding the failure to submit a supplemental application for EtO sterilization. No further regulatory action was necessary since the sponsor obtained FDA approval.

2. On 1/13/84, Intermedics was issued a letter regarding the distribution of various lenses without obtaining approval through a supplemental application. No further regulatory action was necessary since approval was obtained.

3. On 8/11/82, Surgidev was issued a letter regarding their failure to submit a supplemental application for new lens styles. No further regulatory action since the sponsor obtained approval.

4. On 12/7/79, Copeland and CILCO were issued notice of adverse findings letters regarding: (1) a clinical investigator implanting lenses under both sponsors' investigations prior to obtaining FDA and IRB approvals; and (2) deficiencies in the informed consent documents. Both sponsors brought the investigator into compliance, obtained approvals and revised the consent document; no further regulatory action was necessary.

5. On 1/17/83, IOPTEX was issued a letter regarding the expansion of the trial study from 150 patients to 950 patients without obtaining FDA approval. FDA required the sponsor to: (1) cease further shipments; (2) notify all investigators to cease implantation; (3) submit specific data within 30 days; and (4) submit data on other lens studies within 30 days. The sponsor met the requirements of this letter and no further implants were permitted. No further regulatory action was necessary.

6. On 8/11/82, Surgidev was issued a letter regarding changes made in two lens styles without submitting a supplemental application and obtaining FDA approval. The sponsor submitted the supplemental application and obtained approval. However, restrictions were placed on the number of lenses to be implanted; no further regulatory action was necessary.

7. On 5/31/79, McGhan was issued a notice of adverse findings letter regarding shipping lenses to an unapproved investigator. The sponsor obtained approval for the investigator; no further regulatory action was necessary.

Section 813.46:

1. On 6/20/78, Precision Cosmet was issued a letter regarding inadequate monitoring and lack of documenting informed consent. No further regulatory action was necessary since the sponsor resolved the issues.

2. On 9/22/80, Intermedics was issued a letter regarding a traveling investigator who implanted 1639 lenses nationwide and had a 78% lost-to-follow-up rate. The sponsor was required to limit the investigation to investigators who would closely follow all patients. No further regulatory action was necessary since the investigator was not permitted to implant and previous subjects were followed by other investigators.

3. On 5/11/82, Precision Cosmet was issued a letter regarding an investigator who implanted IOLs and had subjects from around the country. The subjects were subsequently lost-to-follow-up. The sponsor was required to assure follow-up of all subjects enrolled in the investigation. No further regulatory action was necessary since the subjects were followed by other investigators.

4. On 2/6/79, Coburn was issued a notice of adverse findings letter regarding deficiencies in records required to be kept by the sponsor, i.e., no post-operative exam records, and shipment of lenses without approval. The sponsor made the corrections in record deficiencies and ceased shipment of unapproved lenses; no further regulatory action was necessary.

5. On 2/9/79, IOLAB was issued a notice of adverse findings letter regarding unaccountable shipment records and labeling deficiencies, i.e., sterilization shelf-life discrepancies. The sponsor corrected the shipment records and revised the labeling; no further regulatory action was necessary.

6. On 2/12/79, Copeland was issued a notice of adverse findings letter regarding an investigator's missing patient records and not maintaining the required records. The sponsor brought the investigator into compliance with the recordkeeping requirements; no further regulatory action was necessary.

7. On 3/30/79, Surgidev was issued a notice of adverse findings letter regarding an investigator's inconsistent recordkeeping and control over the lenses. The sponsor brought the investigator into compliance with their responsibilities; no further regulatory action was necessary.

8. On 5/31/79, Medicornea was issued a notice of adverse finding letter regarding deficiencies in their recordkeeping and deficiencies in an investigator's recordkeeping and lack of reports. The sponsor corrected their records and brought the investigator into compliance; no further regulatory action was necessary.

9. On 6/11/79, Medical Workshop was issued a notice of adverse findings letter regarding discrepancies in subject records and lack of quarantine of defective lenses from lenses waiting for shipment. The sponsor corrected their records and isolated the necessary lenses; no further regulatory action was necessary.

10. On 7/15/81, Medical Workshop was issued a letter regarding the high adverse reaction of hypopyon. The sponsor issued a recall of all remaining lenses and terminated the investigation.

Section 813.50:

1. On 5/25/83, Precision Cosmet was issued a letter regarding promotional language in the device labeling. No further regulatory action was necessary since the sponsor corrected the labeling.

2. On 11/29/82, Americal International was issued a letter regarding misleading labeling, i.e., sizing of lenses and unapproved safety claims. The sponsor revised the labeling; no further regulatory action was necessary.

3. On 5/23/83, Copeland was issued a letter regarding misleading labeling, i.e., misuse of the term "UV" and sizing of lenses. The sponsor revised the labeling; no further regulatory action was necessary.

4. On 7/18/83, CILCO was issued a letter regarding labeling deficiencies, i.e., safety claims, inappropriate caution statement, and reference to "FDA approved" products. The sponsor corrected the labeling; no further regulatory action was necessary.

5. On 9/29/83, Optical Radiation Corporation was issued a letter regarding inaccurate lens sizing information in the labeling. The sponsor revised the labeling; no further regulatory action was necessary.

6. On 12/2/83, Lynell was issued a letter regarding inappropriate placement of caution statement in the device labeling. The sponsor revised the labeling; no further regulatory action was necessary.

7. On 9/27/83, Precision Cosmet was issued a letter regarding distribution of promotional material on the investigational lens at professional meetings. The sponsor revised the literature to delete all promotional statements; no further regulatory action was necessary.

8. On 9/30/83, CILCO was issued a letter regarding distribution of promotional material on the investigational lens at professional meetings. The sponsor revised the literature to delete all promotional statements; no further regulatory action was necessary.

9. On 5/22/83, Intermedics was issued a letter regarding distribution of promotional information on the investigational lens. The sponsor revised the literature; no further regulatory action was necessary.

10. On 12/24/80, 12 manufacturers of IOLs were issued letters concerning advertisements in professional journals and FDA's interpretation of the regulation.

11. On 2/3/83, Surgidev, Corp. was issued a letter regarding the promotion and advertising of a lens before PMA approval. No further action was taken.

12. On 9/30/83, CILCO was issued a letter regarding an exhibit at a professional meeting at which brochures were distributed alluding to safety and effectiveness of a lens. The firm agreed to halt further distribution and no futher action was taken.

Section 813.65:

On 2/1/80, Coburn Optical Industries was issued a letter regarding review and approval of their investigation by an IRB not conforming to the required review procedure. No further regulatory action was necessary since the sponsor resolved the issue with the IRB.

Section 813.2:

1. On 6/28/78, IOLAB was issued a letter regarding the determination that the model [redacted] is not a custom device and is subject to Section 813. No further regulatory action was necessary since the sponsor resolved the issue.

2. On 4/25/78, Intermedics was issued a letter regarding the need to comply with the IOL regulation, effective February 9, 1978. No further regulatory action was necessary since the sponsor brought the investigation into compliance with Section 813.

Section 813.150:

On 4/27/79, the [redacted] was issued a letter regarding the laboratory's refusal to permit inspection, and that any studies performed by the laboratory would not be accepted by FDA in support of the investigation. The laboratory permitted inspection; no further regulatory action was necessary.

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

JUL 11 [illegible]

The Honorable Claude Pepper
Chairman, Select Committee on Aging
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your recent letter requesting the Health Care Financing Administration (HCFA) to provide information on a number of issues involving cataract surgery. The information you requested is as follows.

1. Medicare information by procedure for cataract surgery is currently available for inpatient hospital care only. Information by procedure for physicians' services (recently collected for the first time for 1983 services) is not yet available. Data on procedures for outpatient hospital services are not collected.

   Data for inpatient hospital procedures for DRG 039, Lens Procedure, (includes all cataract surgery) are available for calendar year 1981 and fiscal year 1984.

DRG 039	Number of Cases	Average Charge Per Case
	(000)	
Calendar year 1981	332	$ 1,639
Fiscal year 1984	409	2,344

   Please note these limitations of the data:

   a. Data for fiscal year 1984 is still incomplete due to lags in submissions to HCFA's central statistical processing areas;

   b. Average costs for surgical procedures are not available for 1984. However, we have provided average charges for DRG 039 which encompasses all cataract surgical procedures for both 1981 and 1984.

   c. Similar data for 1982 and 1983 are not available.

2. Outpatient cataract surgery is covered under Medicare. In recent months, attention has focused on outpatient cataract surgery because more and more Utilization and Quality Control Peer Review Organizations (PROs) are screening claims for cataract surgery to assure that they are performed in the appropriate setting. HCFA is in agreement with the PRO review of cataract surgery and closely monitors all of their objectives, activities and the effect on Medicare beneficiaries.

As you know, Medicare review requirements are established by local PROs. The purpose of the PRO program is to assure that the care provided to Medicare patients is medically necessary, is provided in the appropriate setting, and meets professionally accepted standards of patient care quality. In that regard, each PRO must meet certain objectives designed to provide that assurance. One of those objectives is to reduce hospital admissions for elective procedures that could be performed effectively, and with adequate assurance of patient safety, in an ambulatory surgical center or on an outpatient basis.

Medical authorities agree that many lens procedures which are now performed on Medicare patients on an inpatient basis can be safely, effectively, and more economically performed on an ambulatory basis. As a result, over 30 PROs have an objective to shift lens procedures from the inpatient setting to the outpatient setting where that setting is appropriate.

Screening criteria are developed by PRO physicians. They are used by the PRO to approve payment for cases which clearly meet accepted standards and to refer questionable cases to physician reviewers. The PRO physician reviewers, who are actively practicing physicians in the State, make their determinations based on their own knowledge, experience, training, and on discussions with the attending physician for the case being reviewed. In making a determination about the appropriateness of inpatient versus outpatient cataract surgery, the PRO physician reviewer must evaluate all the circumstances which may impact on the medical care in a given case. This involves taking into consideration the medical condition of the patient before surgery, as well as the needs of the patient following surgery and other extenuating circumstances. The screening criteria, however, only apply to elective surgery. Patients with emergencies are always admitted whether or not the PRO has performed its review.

When a denial is made, the PRO program provides a comprehensive reconsideration and appeal process to protect the interest of Medicare patients. The patient, his representative, the hospital, or physician has the right to request a reconsideration if dissatisfied with a PRO's decision.

3. Payment for the intraocular lens (IOL) is not part of the ambulatory surgical center (ASC) facility rate, but rather, is made under the prosthetic device provision. Carriers do have a uniform approach to payment for IOLs which involves application of the Medicare program's reasonable charge principles. These principles involve the calculation of a customary charge and a prevailing charge based on actual charge date of physicians or suppliers. In addition, carriers have discretion to make inherent reasonableness determinations in setting the reimbursement rate for IOLs.

4. A HCFA investigation of available data showed that the vast majority of cataract surgery is performed on either an inpatient or outpatient hospital basis. The trend is toward one day inpatient surgical stays. Payment for

intraocular lenses is not an issue in these instances. The cost of lenses is included in the DRG for inpatient cataract surgery. When the hospital provides the lenses for outpatient surgery, cost reimbursement is the basis of payment. Although the physician could provide the lenses for outpatient surgery and bill on a reasonable charge basis, this is rarely done. Thus, there is little potential for savings through administrative action by HCFA or its contractors.

5. There is no official HCFA position on the reasonableness of surgeon fees for routine cataract surgery. However, there is concern that certain procedures have become overpriced in relation to the time, effort and risk involved due to the development of new procedures and technologies. HCFA will be contracting for studies to develop a relative value scale on the cost of producing physician services for possible use under current legislative authority or as part of overall physician reimbursement reform.

6. HCFA's policy states that the use of the services of an assistant surgeon in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community. The reasonable charge for the services of an assistant surgeon may not exceed 20 percent of the prevailing charge, as adjusted by the economic index, for the surgical procedure. This limitation applies to reasonable and necessary services of assistant surgeons in all settings.

7. The prospective rates of payment for ASC facility services now in use were established in 1982 based on a relatively small sample of the operating costs and charges for services of ASCs in existence at the time. While we believe that the rates are generally appropriate, we also believe there is reason to review the rates to determine whether any changes are indicated by current operating cost data and other fiscal information. HCFA is developing a survey to obtain cost data from all participating ASCs in order to do the review.

8. Nothing in those portions of the Medicare law and regulations which deal with civil rather than criminal matters and for which HCFA is responsible precludes a hospital from routinely waiving payment of deductible and coinsurance amounts for hospital services. Such waiver precludes Medicare payment for the waived deductible and coinsurance as a bad debt but does not otherwise reduce Medicare payments to the hospital. The Office of Inspector General (OIG), however, views such waiver as a possible criminal violation of the bribes, kickbacks, and rebates provisions of section 1877(b) of the Social Security Act. The OIG is currently working toward resolution of this issue with the Department of Justice.

Under the law (section 1833 of the Social Security Act), payments from ASC facility services are not subject to deductible and coinsurance. Also, the payments for the related surgical services by the physician are not subject to the deductible and coinsurance if the physician accepts assignment. (This would also be true if the same surgical services were performed by the physician on an outpatient basis in a hospital.) Thus, no question of a possible civil or criminal violation should arise regarding the provision of "no cost" cataract surgery to beneficiaries in an ASC.

I hope the information we have provided is helpful to you. [illegible] can be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

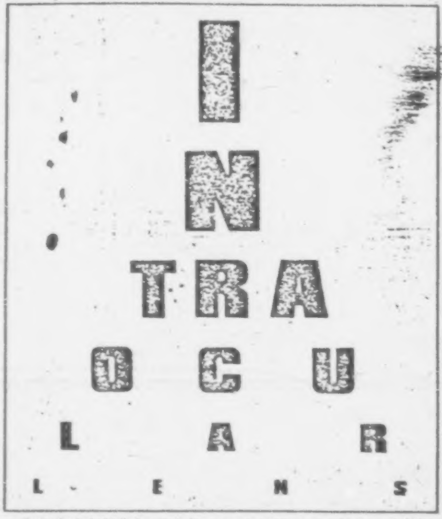
Carolyne K. Davis

Carolyne K. Davis, Ph.D.

Cutting Edge of Eye-Tech

A Close Look at IOLs, the Latest Speculative Favorite

By JAYE SCHOLL



LOS ANGELES—Stretched along a wide, hot valley in Southern California is a string of pioneering medical companies which have proven remarkably adept at surviving in a hostile high-tech environment. This 30-mile swale, located to the east of Los Angeles, is the center of the intraocular lens industry. Inevitably, it has been dubbed "IOL Valley."

This year, the IOL industry will sell $240 million worth of its lenses. Most will be implanted in the eyes of elderly patients following cataract surgery. Implants are such a popular alternative to wearing either thick-lens glasses or contact lenses that 80% of all cataract procedures now involve IOLs. Demographics suggest the market for IOLs will expand rapidly over the next decade. Estimates are that IOL sales will hit $700 million by 1990, when the number of IOL implants in the U.S. is expected to reach 800,000 per year.

Some 30 companies worldwide manufacture IOLs, but the field is dominated by large medical companies which muscled into the market by acquiring much smaller outfits in the late 'Seventies. The undisputed leader in IOL sales is Johnson & Johnson's Iolab, which industry watchers reckon sold $60 million worth of the artificial lenses in 1983. (The company does not break out revenues figures for Iolab.) A research report by the securities firm, Hambrecht & Quist, ranked the other major players thusly: second, the Rorer Group's Cilco with IOL sales of $41 million; third, Intermedics with $31 million in sales, American Hospital Supply's American Medical Optics unit was fourth, with sales of $23 million, and Precision-Cosmet, the contact lens company acquired by Frigitronics, with sales of $21 million, fifth.

Positions can shift quickly, though, because this is an industry driven by two forces: innovation and all-out marketing. Then too, for all its high-tech image, the barriers to entry are low while the rewards are high, a combination which has persuaded more and more companies to start making IOLs. To stay on top of the heap, the major companies spend an average of 10% of their revenues on research and development. But big R&D budgets alone can't guarantee continued dominance. With just one new lens, much smaller companies have shown they are capable of making a splash.

Prospects for rapid growth and the glamour of "eye-tech" have put IOL companies in Wall Street's speculative spotlight and their shares sell at eye-popping price/earnings ratios. Particularly the "pure plays." Optical Radiation Corp., for instance, while off from its April high of $40 a share, still trades at 32 times its fiscal 1984 July earnings of $7.85 million, or $1.05 a share. Another "pure play," Staar Surgical, is operating at a loss, but investors obviously have high hopes for its future.

In recent weeks, the over-the-counter stock has traded for as much as $39 a share and, even after a precipitous fall, is still changing hands around $20.

Both Optical Radiation and Staar have entered a fiercely competitive market with two of the most talked-about lenses in the industry. In 1982, Optical Radiation introduced a lens which blocks ultraviolet light. By 1984, the company's lenses, led by the UV400 IOL had captured an impressive 15% of the IOL market.

For its part, Staar Surgical has developed a lens made of silicone. The soft, rubber-like material permits the lens to be folded in half before it is inserted, theoretically requiring a smaller incision in the eye. The foldable aspect of the lens has earned it the name "Mazzocco Taco," after its inventor, Dr. Thomas Mazzocco of Van Nuys, Calif.

What has whetted Wall Street's appetite for the shares besides an expanding market and that old high-tech magic are the lush profit margins on intraocular lenses. The latter sport $200-$400 price tags, though they cost an average of $40-$60 to make. Many analysts, moreover, cheerfully predict that prices will remain firm or even rise in the years ahead.

Leading ophthalmologists and marketing executives of IOL companies, however, scoff that analysts and investors alike may be peering at the field through rose-colored glasses. The IOL industry, they contend, is beset by pressure to reduce prices because of competition and regulatory forces. As for some of the newer products, these critics contend, they are unproven and may pose unnecessary risks.

"I think the prices and profits will come down in two or three months," predicts Dr. Walter Stark, professor of ophthalmology at John Hopkins Hospital's Wilmer Institute and chairman of the Food & Drug Administration's Ophthalmic Devices Commission, the board which approves IOL lenses. "Doctors aren't thinking about the cost of lenses, but hospital administrators are because hospitals are losing money on these procedures."

Depending on local charges, hospitals are reimbursed between $700 and $1,700 by Medicare for cataract procedures. Hospitals are appealing to the Commission on Prospective Payment Assessment to increase the amount, making the point that the flat reimbursement rate was set in 1981 when only 20% of the cataract procedures involved implanting IOLs. The commission is not expected to make a recommendation until next spring at the earliest, and in the meantime, hospitals are losing money on the operations. In turn, they are pressuring doctors to shop competitively for lenses. "These companies sell the same lenses to Europeans for a lot less," points out Dr. Stark.

In fact, price-cutting, direct and indirect, is already visible. Because of the competition, IOL companies are using questionable sales tactics that have not only provoked a price war, but may have infected the integrity of the ophthalmology profession as well.

Last December, the administrator of of the Health Care Financing Administration sent letters to medical insurance companies saying that "it has come to our attention" that "some manufacturers of intra-ocular lenses and related products are furnishing products to ophthalmologists at no charge in exchange for purchasing their products." The letter cited the anti-kickback provision of the Social Security Act, which forbids hospitals and physicians from accepting free items and not reflecting those savings in bills to insurers. A second letter with a similar warning was sent to the IOL companies.

At the most innocent level, companies offer free surgical accessories, called surgical packs, if a doctor or hospital buys one of its lenses. Pharmacia A.E., a Swedish medical company with operations in New Jersey, includes a disposable syringe filled with Healon, a clear liquid which helps maintain the shape of the eye during surgery, and disposable sponges and knives. The pack is worth about $75, according to James Largent, marketing director of Pharmacia's ICL division. Including the pack brings the cost of Pharmacia's IOL down from $325 to $250, he says. Largent adds that it is up to the hospitals or the surgeons to account for the savings in their billing.

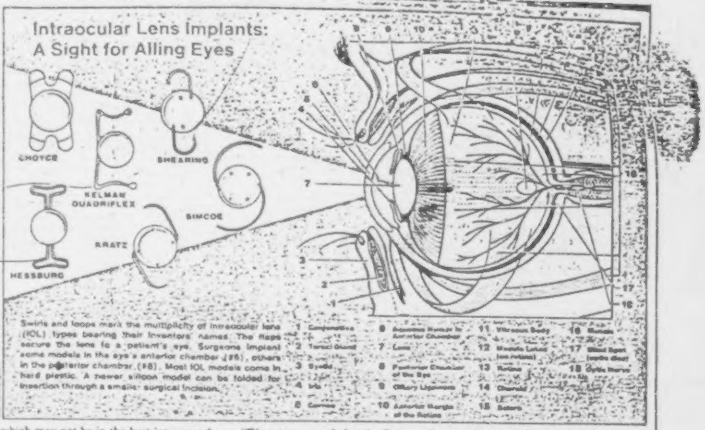
Hospital administrators, however, are apparently confused about how to deal with these "incentives." And their policies range from nonchalance to strict refusal to accept them. Richard Norling, for example, administrator of the California Hospital Medical Center in Los Angeles, argues that the notion of accounting for incentives in Medicare billing is "inconsistent" with the goals of the prospective reimbursement system. "We get a flat fee for procedures. The whole point is to do these procedures as cost-effectively as possible. We certainly would not credit Medicare," he says.

Seth Ellis, administrator of Beverly Hills (Calif.) Medical Center, notes that in return for purchasing CooperVision's IOLs, his hospital gets free surgical packs or a break on the $1,000-a-month leasing fee on its phacoemulsification machine. The latter is a device which uses ultrasound vibrations to turn cataracts into a jelly-like substance before extraction. He says his hospital doesn't credit Medicare either, but instead, gives some of its poorest patients (of which he has many) free IOL implants.

Morrison E. Chamberlin, chief executive officer of Hollywood Presbyterian Medical Center, on the other hand, says that his hospital accepts absolutely nothing for free. "The practice, in my opinion, involves questionable business ethics."

IOL companies also give hospitals expensive equipment such as YAG lasers. The lasers come in very handy if a post-implant patient finds that the capsule around his new lens has clouded up, something which happens about half the time. By focusing the laser on the capsule, the physician can tear a hole in the membrane, much like pulling a curtain back from the window, and restore vision. First generation YAG lasers cost between $50,000 and $75,000.

"There's nothing wrong with it as long as the hospital gets the YAG laser,"


Intraocular Lens Implants: A Sight for Ailing Eyes

Swirls and loops mark the multiplicity of intraocular lens (IOL) types bearing their inventors' names. The flaps secure the lens to a patient's eye. Surgeons implant some models in the eye's anterior chamber (#6), others in the posterior chamber (#8). Most IOL models come in hard plastic. A newer silicon model can be folded for insertion through a smaller surgical incision.

Michael Langevin

remarks one IOL marketing executive who acknowledges that his company sells IOLs in "packages," sometimes with free surgical kits thrown in, sometimes with sophisticated medical equipment offered as an incentive. "But the problem," he continues, "is the way it's being used. Some of the companies are making deals directly with doctors, i.e., 'If you buy our lens, we will give you personally a YAG laser.' " The fact that cataract surgery, among other procedures, is increasingly being done in doctors' private offices is a trend not lost on the more aggressive companies. Obviously, the doctor becomes a customer to be courted intensely.

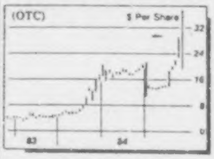
David Karcher, executive director of the American Intraocular Implant Society, based in Santa Monica, Calif., takes a very stern view of any form of discount which cannot be reflected in bills. "How is a hospital supposed to reflect a YAG laser when they're getting reimbursed for a flat fee?"

At a minimum, the "incentives" being offered suggest the degree of elasticity in the prices of IOLs, a factor which will presumably be taken into consideration when the Commission on Prospective Payment Assessment reviews the fee for cataract surgery.

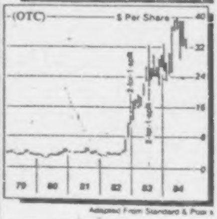
As for offers to surgeons, Karcher said he is well aware of the problems of kickbacks in the IOL business. "I get calls all the time from doctors who asked me if they can accept a YAG laser. I tell them, 'Pay for the damn thing yourself.' " He says physicians also asked whether they can accept free surgical packs. "Our position is that any savings to a hospital or a doctor must absolutely be reflected in their bills."

The scenario bears a disturbing resemblance to the cardiac pacemaker industry of recent years, and not surprisingly, the analogy is made often by both doctors and executives. Some of the cardiac pacemaker salesmen, in fact, also now sell intraocular lenses. While no one has suggested that the IOLs are defective, as some pacemakers have proved to be, concerned observers worry that physicians have been hassled, coaxed and/or cajoled to make decisions which may not be in the best interests of their patients.

Staar Surgical



Optical Radiation



Adapted From Standard & Poor's

Responding to advances in medical technology, for example, physicians are recommending corrective surgery at earlier stages of cataract disease. "You used to wait until you were stone blind," as one surgeon put it. "A lot of patients don't want to wait that long." But there is growing worry that some physicians don't want to wait that long, either.

"I can't believe that the number of operations going on can be attributed solely to the aging population," remarks Dr. Rovert Coles, chief of ophthalmology at Lenox Hill Hospital in New York. Two weeks ago, he says, he gave a second opinion to a "famous decorator" scheduled for an IOL implant last Wednesday. "I can read. I can do everything," the patient told Dr. Coles. After examining her eyes, he agreed. The operation was canceled.

At present, some 30 "models" of intraocular lenses have completed the tortuous approval path mapped out by the Food & Drug Administration. Another 350 or so modifications to those "parent" models are in various stages of approval, but because of a 1978 ruling, these lenses are available to surgeons under the FDA's investigational device exemption (IDE).

With the IDE, lens manufacturers line up physicians around the country who are willing to implant a company's new lens and keep extensive records on their patients' progress. Before the FDA grants approval to market a completely new lens, the company must submit records on at least 500 core implants. Modified lenses, which use proven materials, require about 100 tests.

Because of swift changes in the industry, both in terms of technique and fashion, IOLs quickly become outdated. "It's like hemlines," quips Dr. Coles, who adds that many of the 400 lenses available are "antiques." The absence of a clearly superior lens, coupled with the prospect of enormous profit margins, has created a free-for-all among lens manufacturers. In the Rockville, Md., offices of the Food & Drug Administration, at least 500 additional lenses are awaiting the agency's imprimatur.

"We are overwhelmed. Swamped isn't the word for it," admits one of the FDA's reviewers. Because of budget cuts and the blizzard of applications, reviewing the manufacturing process is backlogging a year or more. "The staff is in no way able to keep up," he says.

Until now, the short but explosive life of the IOL industry has been dominated by hard lenses made of a plastic called polymethylmethacrylate, or PMMA. The use of PMMA dates to the 'Forties, when Royal Air Force surgeon Harold Ridley observed that shards of plastic from exploding fighter plane cockpits remained inert in pilot's eyes. Though the leap to using PMMA for artificial lenses was swift—Dr. Ridley implanted the first PMMA lens in 1949—the evolution of surgical approaches has been circuitous. At first, ophthamologists inserted artificial lenses behind the iris, then in front of it, and since the mid-'Seventies, again in back of the iris.

Today, the most common procedure is the extracapsular extraction, or ECCE, in which surgeons remove the portion of the lens located behind the iris. Although more complicated, ECCEs can be done with a much smaller incision in the eye.

As techniques have advanced, however, Dr. Ridley's observation has remained constant: PMMA material has no deleterious effects on the eye, even after 40 years. No matter how safe competing lens materials ultimately prove to be, it will be years before they can make claims as convincing as those for PMMA.

That hasn't stopped companies from trying, however. Following an implant demonstration for ophthalmologists in Houston last week, Staar Surgical issued a press release on the results of its new foldable lens with the headline, "It Works," and quoted Dr. Mazzocco as saying "Silicone appears to be the ideal bio-compatible material for IOLs."

"You have to take press releases with a grain of salt," comments Dr. Mazzocco, "but we think it's one of the best bio-compatible substances we see."

Mazzocco points out that there is a 25-year history of using silicone in human tissue and he says tests on animals indicate that it will be just as benign when used as a lens. The ultimate point of using silicone rather than PMMA, however, is its malleable quality. Instead of a six-millimeter incision, the "plastic" lens can be inserted through a three-millimeter cut. Until the FDA gets more data on the reaction of silicone, however, the agency has told Staar to postpone the three-millimeter procedure.

A total of 70 of Dr. Mazzocco's lenses have been implanted since April, when Staar received an investigational device exemption from the FDA. The problems, he says, have been limited to instances where surgeons attach the lens to the eye's capsule, resulting in a shifting of the lens after surgery. This was easily corrected, he reports, but the recommendation to doctors now is to attach the lens to a more stable part of the eye.

While Staar Surgical waits for its intraocular lens to work its way through the FDA approval process, however, it must take care of more pressing matters. These pressing matters are financial rather than technical.

In the first six months of 1984, the Monrovia, Calif.-based company suffered a loss of $890,000, or 65 cents a share, on revenues of $328,953. Cash has dwindled from $1.8 million at the beginning of the year to $422,000. In the words of Staar Surgical's second quarter report, the negative cash flow indicates "liquidity problems in the near future." Management, the report continues, "is actively pursuing additional long-term financing."

These cold compresses would ordinarily be enough to chill the feverish enthusiasm of the boldest of investors. But two days after the discouraging June quarter ended, Staar authorized a 2-for-1 stock split, creating a total of 2,723,000 shares, to meet "strong demand" for its stock. The latter, which was offered at $10.25 when Staar went public in July 1983, split at $21. As noted, it hit $39 in recent weeks, and now trades around $20.

One explanation for the sharp swings in the price of Staar's stock may be the involvement of First Jersey Securities,

Continued on Page 24

REENTRY INTO GROWTH

Continued from Page 22

ellites and cable, it doesn't do the job very vigorously and the deregulators at the commission have said they'd like to drop it altogether when competitive conditions permit. That could pose a problem, since AT&T plans to lay its first-capacity fiber optic cable for service in 1988.

As if competing against AT&T wouldn't be enough, U.S. communications companies, such as Western Union and RCA, sought FCC permission to deal directly with Intelsat, bypassing Comsat.

To take it further, if competing against all its existing customers wouldn't be enough, two new companies, Orion Satellite Corp. and International Satellite Inc., are clamoring to build their own transatlantic satellites to compete against Intelsat. These could be a success because Intelsat charges represent a system-wide average, which means the big-volume transatlantic rates are kept high to subsidize low-volume service elsewhere in the world. Competitors would be under no such stricture.

If all three proposals went through, Comsat's international monopoly would be destroyed. All its customers would be competitors and its supplier would be undercut on price.

Happily for Comsat, things are looking up on two of the three competitive international fronts. In April, the FCC passed a ruling letting U.S. carriers deal directly with Intelsat, preserving the Comsat monopoly. Intelsat has been conducting a diplomatic lobbying campaign against those would-be rivals that seem to be taking hold.

Even the competition from the AT&T cable looks no more threatening than it did. FCC officials indicate they expect to keep regulation at least in part: they will not allow AT&T to engage in predatory competition.

One measure of the continued competitiveness of the Intelsat system is the way Comsat keeps bumping up against the 14% allowable rate of return, bringing FCC-mandated rate cuts. The latest one was a 5.8% decrease July 31, which Comsat's critics greeted with a grumble that it would hit earnings for about 40 cents; more properly, they should have sent up a cheer for the strength of one of the company's vital signs.

In sum, despite Wall Street's current skepticism, the picture at Comsat has brightened considerably, thanks to elimination of the continuing losses at SBS and continued strength in the monopoly businesses. Not to be overlooked, either, is renewed vigor in Comsat's U.S. domestic satellite business and promise of profitability in 1985 in the electronics businesses that have been a 20-cent to 30-cent a share pretax drain for several years. And, who knows? One or two of Comsat's more speculative ventures might get into orbit one of these years as well. ■

CUTTING

Continued from Page 9

an aggressive securities firm, as one of its market makers. As readers of *Barron's* know, First Jersey Securities has been accused by the Securities and Exchange Commission of manipulating markets in small, thinly traded over-the-counter stocks.

"They're making a nuisance of themselves," snaps Thomas Waggoner, president of Staar Surgical. But as he points out, there are at least five other market-makers in Staar, the presence of whom dilutes First Jersey's influence.

Waggoner says that negotiations with Kidder, Peabody for additional financing are continuing, and that he has "firm commitments" for capital from other sources. "We've had to scale back and postpone a couple of things, but I can smell break-even," he confides.

If break-even is in the offing, it won't be from sales of the elastic lens, which are at least two years away from winning full FDA approval. "If it works, I expect there will be a lot of 'me too' products," says Waggoner, "but we'll have at least a six-month headstart." Staar has two patent applications pending for its lenses, but even Waggoner downplays their importance. "To be honest, patents are not worth much."

In the meantime, Staar is pursuing related businesses. It has developed a conventional PMMA lens, a phacoemulsification machine, which uses ultrasound vibrations to remove clouded lenses, and disposable surgical kits used during IOL implants. "We're tight," is the way Waggoner described his company's cash situation, "but we don't need money to survive, just to expand."

But in each of these markets, Staar faces stiff competition—Johnson & Johnson's Iolab, Rorer Group's Cilco division, Pharmacia's Medical Workshop, Frigitronics' Precision-Cosmet and American Hospital Supply's AMO are just some of the companies making PMMA lenses, for example. A number of these companies report that they are working on three-millimeter lenses as well.

In addition to companies, surgeons themselves are developing new lenses. Dr. Charles Kelman, inventor of the aforementioned phacoemulsification process and something of a wunderkind in the IOL world, claims that he has developed a three-millimeter lens, and that it

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CUTTING EDGE

Continued from Page 24

will be available to surgeons for test implanting by spring. Kelman, who already has a bunch of IOLs bearing his name, says his lens is made of PMMA. Using a proven plastic material will be the key, he believes, to rapid acceptance in the marketplace, not to mention an easier path to FDA's approval.

Because of the shifts in IOL preference, companies with a new product can quickly establish a market presence. Thus, Optical Radiation took the industry by surprise with its introduction of the first ultra-violet absorbing lens. Using a material which is bonded to PMMA, the lens blocks 99% of the ultra-violet light.

To patients whose natural lenses were about to be removed, Optical Radiation's UV blocker was an instant hit. For the first time, surgeons had patients demanding a particular brand of IOL. Spurred by the success of the lens, Optical, which is into various other eye-tech and high-tech products, saw revenues soar from $18.5 million in fiscal 1982 (ended July) to $26.6 million in fiscal 1983 and $48.2 million last fiscal year. Earnings per share shot up from 21 cents in fiscal 1982 to 47 cents the following year and $1.05 in fiscal 1984, or some 120% over last year.

Because of the clamor over UV lenses, other companies swiftly set about developing their own—Cilco, Iolab and American Medical Optics, among them. Wedged between this battle for UV market share, however, are the surgeons, many of whom say they buy UV lenses because their patients ask for them, not because they believe in them.

For despite the publicity and the claims made for UV lenses, there is no medical evidence—just a lot of opinions—that ultraviolet light damages the eye's retina, according to Dr. Stark, chairman of the FDA's Ophthalmic Device panel. Even IOL companies executives question the validity of the concept. "The whole UV business [illegible] marketing hype," concedes one director of an IOL division, who adds that his company nevertheless introduced just such a lens to thwart the competition.

Even if the competition has already cut into Optical Radiation's share of UV lens market, its dominance is such that most analysts predict continued increase in sales through 1985, and possibly an even greater share of the UV market. But Optical Radiation, like its rivals, will face additional pressure to reduce the prices of its lens, not only from regulators, but from an inevitable slowdown in the growth of the market.

Whereas five years ago only a quarter of cataract operations used IOL implants, today that figure is over 80%. The growth has clearly been explosive. But just as clearly, there is a limit. Most doctors reckon that the market will increase to a maximum of 95% of all cataract operations within two years. But from that point on, old competitors and new entrants alike will be splitting a market whose growth will largely be determined by demographics. Some opportunities exist in selling more lenses abroad, but as mentioned, the price of IOLs in Europe is about half of the U.S. price.

In fiscal 1983, IOL sales accounted for about one-third of Optical Radiation's revenue. The acquisition of Omega Optical, a leading laboratory processor of ophthalmic lenses could dilute that contribution this year. In 1985, its fans estimate, Optical Radiation should earn $1.60 a share, and $3 in '86.

Amid all the excitement over ultraviolet light blockers and three-millimeter lenses, however, some physicians are taking a much more jaundiced view. Dr. Stark, for one, says he reacts "very, very cautiously" to these new developments.

"Modifications have often led to serious problems. Some IOLs have been taken off the market. What concerns me is the addition of new substances to lenses." No one knows, he says, whether the material added to lenses to make them block ultraviolet light will prove safe; as far as he is concerned, the advantages do not outweigh the risks.

"New things are nice to talk about, but if you put [UV blockers] in the eyes of young people 30 to 40 years old," observes Stark, "you have to look at it very cautiously. Ultraviolet light can be blocked by glasses, which is what I'd rather wear."

As for three-millimeter lenses, he's of the opinion that while they may be innovative, they don't offer a great benefit. "Whether it's a three-millimeter or five-millimeter incision makes no big difference. We're not having problems treating the wound." And, he adds, there are also no problems with ultraviolet light. "It really irritates me. Basically, doctors with a financial interest and the companies are behind it. It's a big promotional thing." ■

APPENDIX E

July 30, 1984

TWENTY MILLION PEOPLE IN UNDER-
DEVELOPED NATIONS ARE BLIND FROM
CATARACTS. THESE MILLIONS CAN
SEE AGAIN WITH SURGERY AND AN
I.O.L.

Dear Doctor,

Can you imagine never seeing your children or grandchildren? If you were in this condition what would you give to be able to see again? Many of us desire to help but we need direction.

has given thousands of lenses away per year for the needy. We need to do more. These are our ideas;

#1. For every lens implanted and paid for by your clinic or hospital, will fund up to eighty dollars per lens (amount depends on whether your clinic or hospital receives a volume discount). These funds can be directed to your church, SEE (Surgical Eye Expeditions), Orbus, or directly to a foreign clinic for surgical microscopes, drugs, air fares for you to fly to these places to operate and instruct, or for whatever charity you decide upon. will also provide I.O.L.s at no charge.

#2. If you desire to use another brand of I.O.L.s in your clinic, we will still give you I.O.L.s for any overseas philanthropic endeavor.

If only two hundred doctors in the U.S.A. become partners with us in this work we can fund the free eye clinics over $1,000,000 per year.

#3. If a poor patient in the U.S.A. is not covered by medicare or any health program, will provide a lens at no charge, upon request. If you will do the surgery at no cost.

If you desire more information, please call the Chairman of Charities, Mr.

[redacted], 1984

[redacted] Hospital [redacted]
[redacted]

Dear [redacted]

In response to your phone call earlier today, I have revised our [redacted], 1984 proposal to [redacted] Hospital [redacted] to reflect an anticipated increase in implant volume from your hospitals. The new bid proposal includes the intraocular lens styles listed below:

Lens Style	Chamber	% Discount	Their Price	Discounted Price/Lens	Now Contract Price
[redacted]	Anterior	58%	325.00	$138.00	163.00
[redacted]	Anterior	58%	325.	$138.00	163.
[redacted]	Posterior	58%	325.	$138.00	163.
[redacted]	Posterior	58%	325.	$138.00	163.
[redacted]	Posterior	58%	325	$138.00	163
[redacted]	Posterior	58%	325.	$138.00	163
[redacted]	Posterior	58%	350.00	$147.00	175.00
[redacted]	Posterior	58%	375.00	$158.00	188.00
[redacted]	Posterior	58%	375.00	$158.00	188.00
[redacted]	Posterior	58%		$158.00	
[redacted]	Posterior	58%		$158.00	
[redacted]	Posterior	58%		$158.00	
[redacted]	Posterior	58%		$158.00	

- [redacted]

This bid proposal was prepared using a revised volume projection of 125 intraocular lens implants/month. Should the total average monthly implants change significantly from this projection, the discounted prices will be reviewed and adjusted according to the attached schedule. An initial three month grace period will be permitted for [redacted] Hospital [redacted] members to allow these hospitals the opportunity to become familiar with [redacted] intraocular product line and increase their usage of our lenses.

At the risk of being redundant, I have again listed the various services that your member hospitals will receive from [redacted] at no additional charge:

o FREE IN-SERVICE TRAINING WITH CEU credits awarded.

- o NO RESTERILIZATION CHARGE.
- o LOCAL SALES REPRESENTATIVE on call 24 hours a day.
- o INITIAL CONSIGNMENT INVENTORY shipped and set up at no charge.
- o [redacted] - CONSIGNMENT INVENTORY MANAGEMENT SYSTEM, to simplify the record keeping and reordering of IOL's.
- o FREE PATIENT INFORMATION BROCUHRES that explain cataracts and IOL's to your patients.
- o EXPANDED CUSTOMER SERVICE HOURS to better serve your needs. (4 a.m. to 5:30 p.m. PST)
- o ALL PMMA LENS CONSTRUCTION for quality and durability.
- o BLUE PMMA LOOPS for improved visibility by the surgeon during implantation of a lens.

The completion and return of this letter indicates your acceptance of this bid proposal and places the above prices in effect as of the date indicated. The expiration date of this discount agreement will be twelve months from the effective date below and is based on remittance Net 30 days.

Pamela, I appreciate the opportunity of discussing [redacted] Hospital [redacted] specific circumstances with you and look forward to a long working relationship with you and your organization. If you require any further assistance pertaining to this revised bid proposal, please do not hesitate to contact me at 1-800-[redacted].

Sincerely,

DISCOUNT PRICE SCHEDULE

# Implants/Month	# Implants/Year	% Discount
0-4	0-48	10%
5-12	49-144	15%
13-25	145-300	20%
26-42	301-504	25%
43-63	505-756	30%
64-83	757-996	40%
84-124	997-1488	50%
125+	1489+	58%

Dear Doctor:

Ophthalmic outpatient surgery centers are being developed at an astonishing rate. It is estimated that 80% of all ophthalmic surgery will be performed on an outpatient basis by 1987.

Have you ever wondered if an outpatient center is in your future?

Answering that question could be simpler than you think. A leading consulting firm has developed a sophisticated new software program that can generate a financial feasibility study and projected income/cash flow analysis based on your current practice and surgical volume.

All you have to do is provide the input.

There's a questionnaire on the back of this letter. Simply fill it out and mail it directly to [redacted] Corporation. They'll send you an analysis plus a computer generated floorplan of one way your surgery center might look.

This service is underwritten by [redacted] to help surgeons evaluate the direction of their practice. There is absolutely no cost or obligation to you. Please feel free to avail yourself of this information.

Sincerely,

Ophthalmic Outpatient Surgery Center
Feasibility Analysis

Physician Questionnaire

MD
Physician's Name

Address

(
Telephone

City State Zip

To receive a computer generated feasibility analysis of an ophthalmic surgery center for your practice, please complete the following questions.

A. Percentage of your cataract extractions utilizing the following techniques: [illegible] 10 %
ECCE 88 % ICCE 2 %
B. Percentage of your cataract patients receiving an IOL: 95 %
C. Brands of equipment and disposable packs currently used:
PEA (Phaco) unit CooperVision Phaco pack Cooper - Cavitron
I/A unit Cavitron I/A pack Cavitron
D. Percent of your IOLs: ACL 2 % PCL 98 % UV 100 %
E. Type of ambulatory facility contemplated:
Office Based 75 % Free Standing 25 % Hospital Affiliated ________ %

Fill in as many actual factors as possible. Assumed factors will be applied where actuals are omitted.	Assumed Factor	Actual Factor
1. Number of IOLs you (and your associates) implant each month.	20	45
2. Percentage increase in implants you are projecting after opening an ambulatory surgery center.	40%	60
3. Medicare facility fee for cataract extraction with IOL.	$ 530	$
4. Your Medicare surgical profile fee per case.	$ 2,000	$ 2075
Assistant's fee is 20% of profile (enter 0 if none).	$ 400	$
5. Number of cataract cases performed per surgery day.	5	4-7
6. Contract personnel		
R.N. circulator (required)	$ 130/day	$
Surgical technician	$ 30/case	$ ✓
General purpose person (usually available from existing staff)	$ 0/day	$
Full-time employees		
R.N. circulator @ $2,500 per month	$ 0	$
Surgical technician @ $1,800 per month	$ 0	$
General purpose person @ $1,500 per month	$ 0	$
7. Equipment for facility with one O.R. without phaco unit (enter $170,000 for two O.R.'s).	$110,000	$
Additional cost with each phaco unit $40,000.	$ 0	$
8. Building lease per square foot per month.	$ 1.25/mo	$ 12^{00}
9. Space preferred for a facility with ONE O.R. (enter 1,500 for TWO O.R.'s).	1,200 sq ft	1500
10. Percentage of time a visco-elastic agent is used.	10%	100%

Please return the completed questionnaire to:

, 1984

, M.D.

Dear Dr.

Thank you for returning the questionnaire regarding the financial feasibility of developing your own outpatient surgery center. We believe the resulting enclosed documents will greatly assist you in your planning since they do reflect your personal situation.

The assumptions used to create the income statement and cash flow schedule reflect current construction and supply costs, costs of capital and federal reimbursements.

The analysis is conservative in that it reflects only cataract cases with implant and a small percentage of other procedures reimbursed under Medicare. Perhaps the addition of a laser room and the acquisition of YAG and argon lasers would make such a proposition even more attractive.

You will find the analysis generally self-explanatory but please feel free to call if you have any questions or would like to approach it from, perhaps, a different angle.

We would like to hear from you to further explore the development of your own ambulatory surgery center. Contact any one of our corporate officers: [illegible] or me.

Sincerely,

President

RGICENTER FINANCIAL FEASIBILITY ASSUMPTIONS

· The number of cataract procedures with implant you and your associates) perform each month.			45	
The POTENTIAL percentage increase in surgical volume you can expect after opening your own surgicenter.			60	%
. The MEDICARE facility fee for ECCE with IOL in your area.		$	530	
. Your MEDICARE surgical profile fee per case.		$	2,075	
Assistant's fees @ 20% of profile.		$	415	
The number of cases performed in a day of surgery.			5	
Contract personnel				
R.N. circulator (required)		$	130	per day
Surgical technician		$	30	per case
General purpose person (usually available from existing staff)		$	0	per day
Full-time employees				
R.N. circulator @ $2,500 per month		$	0	per month
Surgical technician @ $1,800 per month		$	0	per month
General purpose person @ $1,500 per month		$	0	per month
Complete equipment package for facility with ONE O.R. including microscope and I/A machine ($170,000 for TWO O.R.s)		$	170,000	
Phacoemulsification unit (add $40,000 each)		$	0	
Equipment lease factor per thousand $ per month			23.48	
Building lease rate		$	1.00	/sq ft/mo
Surgicenter space preferred for ONE O.R. (1,500 for TWO O.R.s)			1,500	sq ft
Capital improvements		$	50	/sq ft
Total cost of improvements in existing shell		$	75,000	
Down payment percentage			0	%
Total down payment		$	0	
Amount subject to permanent financing		$	75,000	
Interest rate (10 year term)			14	%
.Visco-elastic agent	Percentage of cases used 100 %	$	60	/case
.Property taxes as a % of construction cost			1.25	%/yr
.Disposable surgical packs		$	80	/case
.Disposable I/A or phaco packs		$	50	/case
.Medications		$	50	/case
.Insurance (property & liability)		$	100	/mo
.Maintenance ($.25/mo/sq ft)		$	375	/mo
.Utilities ($.25/mo/sq ft)		$	375	/mo
.Start-up capital (SDC fee & 2 months expenses)		$	51,807	

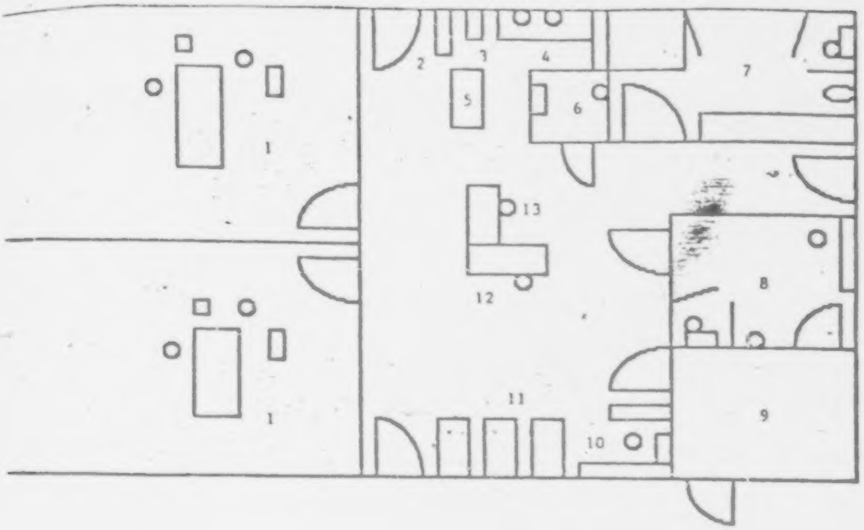
[illegible], M.D.

Copyright 1984 by:

GICENTER INCOME STATEMENT AND CASH FLOW PROJECTION

		Month	Year	Month	Year
ENUE PROJECTION					
Cataract cases with IOL	Number of cases	45	540	72	864
Income from facility fees		$ 23,850	$ 286,200	$ 38,160	$ 457,920
Other facility fees (net)		1,800	21,600	1,800	21,600
TAL REVENUE		$ 25,650	$ 307,800	$ 39,960	$ 479,520
ENSE PROJECTION	Number of surgery days	9	108	14	173
Contract personnel		$ 2,520	$ 30,240	$ 4,032	$ 48,384
Full-time employees (+ 25% benefits)		0	0	0	0
Equipment lease		3,992	47,899	3,992	47,899
Building lease		1,500	18,000	1,500	18,000
Loan on capital improvements		1,164	13,965	1,164	13,965
Property taxes		78	938	78	938
Disposable surgical packs		3,600	43,200	5,760	69,120
Disposable I/A or Phaco packs		2,250	27,000	3,600	43,200
Medications		2,250	27,000	3,600	43,200
Visco-elastic agent		2,700	32,400	4,320	51,840
Insurance (property & liability)		100	1,200	100	1,200
Maintenance		375	4,500	375	4,500
Utilities		375	4,500	375	4,500
AL EXPENSE		$ 20,903	$ 250,842	$ 28,895	$ 346,746
H FLOW		$ 4,747	$ 56,958	$ 11,065	$ 132,774
Less depreciation -(impr/10yr, equip/5yr SL)		3,458	41,500	3,458	41,500
OME BEFORE TAX		$ 1,288	$ 15,458	$ 7,606	$ 91,274
Income tax expense (benefit) @ 50%			7,729		45,637
Investment tax credit			17,000		
INCOME			$ 24,729		$ 45,637
Add depreciation			41,500		41,500
Deduct start-up capital			51,807		
FLOW AFTER TAX			$ 14,422		$ 87,137
ME FROM POTENTIAL INCREASE IN SURGICAL VOLUME				$ 67,230	$ 806,760

SURGICENTER FLOORPLAN, 2 O.R.'S, 1500 SQ FT.



IS SURGICENTER CONTAINS APPROXIMATELY 1500 SQ FT AND THE
LLOWING AREAS:

- TWO OPERATING ROOMS
- SCRUB
- AUTOCLAVE
- CLEAN-UP
- STERILE SUPPLIES
- JANITOR'S CLOSET
- STAFF CHANGING
- PATIENT CHANGING
- PATIENT WAITING
- RECEPTION
- PRE-OP, RECOVERY
- DICTATION
- R.N. STATION

MEDICARE REQUIREMENTS FOR CERTIFICATION INCLUDE:

A) STATE LICENSING REQUIREMENTS
B) STATE FIRE MARSHAL REQUIREMENTS
C) STATE BUILDING CODES FOR A.S.C.'S
D) HANDICAPPED FACILITY LAWS WHERE APPLICABLE
E) H.C.F.A. REQUIREMENTS FOR A.S.C. SURVEY

FOR ASSISTANCE IN PLANNING, CONSTRUCTING AND EQUIPPING YOUR SURGICENTER, CONTACT:

LENS PURCHASE AGREEMENT

Based upon your commitment to purchase a total of ________ lenses from [illegible]. for one year, we agree to discount our list price in effect at the time of the order. The last page of this agreement outlines the current discounted bid pricing.

If, after reading the terms herein, this agreement is acceptable to you, please sign where indicated below and include your purchase order number (or attach a copy thereof) and return to Sales Administration Manager for institution of this pricing. This quotation will expire if not accepted on or before October 11, 1984.

Terms of Sale: Shall be ½ in 30 days, net in 60 days.

Minimum Order Requirements: Lenses may be ordered in any quantities. No minimum orders exist as long as agreed purchase volumes are met. Failure to purchase the agreed quantity will result in, (a) a smaller discount percentage or (b) termination of the entire agreement.

Lead Time: Orders will be processed the same day received or as soon as possible thereafter.

Pricing Guarantee: All discounts are from current list prices. If during the term of this agreement, the list prices of [illegible]. fluctuate, the discount will apply to the new list prices. Any price protection clause in effect as the result of a previously executed Consignment Agreement or Addendum becomes void at the time this agreement is executed.

The following is a list of items covered by this agreement:

MODEL	CURRENT LIST PRICE	CURRENT BID PRICE
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$350.00	$280.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$325.00	$260.00
[illegible]	$350.00	$280.00

Lens Purchase Agreement
Page 4

The following is a list of items covered by this agreement:

MODEL	CURRENT LIST PRICE	CURRENT ~~BID~~ PRICE
	$325.00	$260.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00
	$350.00	$280.00

Thank you for your support of [redacted]. We are pleased that you are interested in our hardware promotional program. As you know, under the program, we would agree to provide you with a piece of equipment in connection with your purchase of our intraocular lenses.

Recently, a number of ophthalmologists received copies of a legal opinion issued by the firm of Leighton, Conklin, Lemov, Jacobs and Buckley to the American Intra-Ocular Implant Society regarding the legality of discounts or rebates on intraocular lenses. It is their opinion that:

1. There is no violation of law in acceptance of intraocular lens discounts, rebates or bonuses by implant surgeons when analyzed under the Social Security Act or under the Food, Drug and Cosmetic Act; but that
2. Intraocular lens discounts, rebates or bonuses must be passed on to third party payers in the Medicare or Medicaid programs when the implant surgeons seek reimbursement; conscious failure to do so may be considered a criminal felony.

Some of our customers have asked how this opinion relates to our hardware promotional program. Our legal counsel has reviewed the program in detail and agrees with the opinion issued by the Leighton firm that it is permissabl to participate in discount or similar programs, but that such benefits shoul be passed on to third party payers in the Medicare and Medicaid programs.

The mechanics of third party reimbursement vary so widely from one ophthalmi practice to another that it is difficult for us to provide specific guidelines as to how the benefit of our hardware program should be reflected in reimbursement claims. Specific treatment should be discussed with your accountant.

We hope this letter will clarify the nature and status of our program. If I may answer any questions or be of any service, please call. Again, thank you for your support of [redacted]

Sincerely,

[redacted]

IOL Marketing Manager

Three Year Purchase Agreement

Intraocular Lenses/Ophthalmic Hardware

---

agreement entered into on ______ by ______

and ______

______ Name

______ Location ______, herein referred to as "Purchaser".

ties of Purchaser

Purchaser agrees to purchase a minimum of [redacted] Intraocular lenses (IOL's) manufactured by ______ within the term of this Agreement.

Purchaser agrees to order a minimum of [redacted] IOL's during each of the first, second and third years of the Agreement,

unless the commitment to purchase a minimum of [redacted] IOL's has been met or exceeded prior to the full term of this Agreement

Purchaser agrees to order a minimum of M690 Wild Microscope IOL's within thirty (30) days of signing this Agreement

Purchaser agrees to pay for IOL's upon receipt of invoice following delivery of IOL's.

Purchaser acknowledges that the unit referred to in paragraph 2 a. of this Agreement constitutes a discount to the purchase price of the IOLs and agrees to reflect this discount to the extent required by Medicare/Medicaid or other third party reimbursers.

reverse

ties of

agrees to provide a [redacted], herein referred to as a "unit", to Purchaser for a minimum of three (3) years from the date of this Agreement provided the Purchaser performs the duties according to paragraph 1 of this Agreement

agrees to transfer the title of the unit to Purchaser at the end of the term of this Agreement provided Purchaser has performed the duties included in paragraph 1 of this Agreement. Title to unit may be transferred to Purchaser at an earlier time if Purchaser has met the full commitment

to purchase a minimum of ______ IOL's

agrees to supply IOL's of styles and powers routinely manufactured by ______ to Purchaser. Purchaser will be invoiced for IOL's shipped to Purchaser at standard list prices and with payment terms which are in effect at the time of receipt of purchase order from Purchaser.

ease of Obligation/Termination of Agreement

Purchaser may release himself from obligations to purchase the previously stated minimum quantities of IOL's by either returning the unit to ______, or by paying ______ an amount not to exceed the then current purchase price of the unit.

If Purchaser fails to perform the duties set forth in paragraph 1 of this Agreement ______ may, at its sole discretion, terminate this Agreement with thirty (30) days prior written notice and repossess the unit

m

m of this Agreement shall be three (3) years from the date of Agreement unless Purchaser or ______ initiates earlier termination as described in paragraph 3

ess Hereof, the parties have executed this Agreement effective the date first set forth above

ser

______ ______

Signature

______

Name (Type/Print)

______

Title

gned Agreement, along with IOL order to ______ at the above address

______ ______

For Assistance Call:
800-526-0355
or
800-343-0577

WILD OPERATING MICROSCOPE WORKSHEET

Prepared for:
DR
, TX

Phone

Prepared by:

SALES REPRESENTATIVE

Phone

NOTE: Boldface Stock Numbers are for M690 Only.

	Stock #	Description	Price	Quantity	Ex-Price
Optics Carriers	MS 411 571	M690 Optics Carrier	$12,110		
	MS 411 571 UV	M690 Optics Carrier with UV Filter	12,159	1	
	MS 399 753	M650 Optics Carrier	4,302		
	MS 399 753 UV	M650 Optics Carrier with UV Filter	4,351		
Microscope Carriers	MS 997 167	X-Y Coupling, M690	$ 7,500		
	MS 411 574	M690 Microscope Carrier with inclining lever	1,369		
	MS 411 575	M690 Microscope Carrier with Drive	1,895	1	
	MS 399 754	M650 Microscope Carrier with inclining lever	813		
	MS 399 755	M650 Microscope Carrier with Drive	1,378		
Tiltable Joints	MS 182 526	Tiltable Joint with infinitely variable brake	$ 781		
	MS 399 765	Tiltable Joint with Drive	1,586	1	
	MS 387 487	Counterweight	120		
Stands	MS 411 570	M690 Floorstand MS-C, Rollable	$11,583	1	
	MS 422 594	Ceiling Mount, MS-F, for M690 (115 V)	28,466		
	MS 415 993	Wall Stand, MS-A, for M690	10,530		
	MS 399 763	M650 Floorstand, MS-C, Rollable	7,036		
	MS 399 761	M650 Wall Stand, MS-A	6,073		
	MS 399 764	M650 Table Stand, MS-D	1,693		
	MS 997 124	Column Extender, 8 inches {For Floorstands Only}	603		
	MS 997 163	Column Extender, 6 inches	289		
Binocular Tubes	MS 382 090	Inclined Binocular Tube, low, with iris diaphragm	$ 1,886	1	
	MS 384 684	Straight Binocular Tube, with iris diaphragm	1,807		
	MS 369 592	Inclined Binocular Tube, low angle	1,638		
	MS 369 588	Straight Binocular Tube	1,411		
	MS 246 900	Inclined Binocular Tube, high angle	649		
	MS 182 503	Inclinable Binocular Tube	4,900		
	MS 404 025	Double Iris Diaphragm	257		
Eyepieces	MS 384 070	Eyepiece, 10X/21B	$ 321	2	
	MS 334 630	Eyepiece, 15X/14B	448		
	MS 377 506	Eyepiece, 20X/11B	455		
	MS 389 170	Spacer Ring, 6mm	8		
	MS 389 171	Spacer Ring, 9mm	8		
Objective Lenses	MS 409 842	Objective Lens f = 100mm	$ 296		
	MS 997 174	Objective Lens f = 150mm	475		
	MS 997 175	Objective Lens f = 175mm	280		
	MS 382 162	Objective Lens f = 200mm	315	1	
	MS 407 743	Objective Lens f = 250mm	311		
	MS 382 168	Objective Lens f = 300mm	295		
	MS 997 179	Objective Lens f = 330mm	452		
	MS 382 172	Objective Lens f = 400mm	284		

Total Page 1 30066
9% TAX + SHIPPING Total Page 2 2,706
Quotation Total 32,77

Date

In Response To DRG-39

[illegible]

offers the

D. R. G. Program

combining Cataract Surgical Supplies

- **I.O.L.'s**
  Complete line of the state-of-the-art lenses
- **I/A Kits**
  CooperVision compatible
- **Free** [illegible]™ **Balanced Salt Solution**
  The standard for years
- **One Year Price Guarantee**

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APPENDIX 2

THE EYE FOUNDATION HOSPITAL

August 6, 1985

The Honorable Claude Pepper
U.S. House of Representatives
377 House Office Building Annex 2
Washington, D.C. 20515

Dear Congressman Pepper:

Thank you for the opportunity to testify on Friday, July 19, 1985, at the "Cataract Surgery, Fraud, Waste and Abuse" hearing. Your staff had asked me to address the effects of group purchasing of intraocular lenses as well as share some recommendations we had regarding problems within the intraocular lens industry.

There appears to have been information shared with members of your committee, as well as those in attendance, that was somewhat misleading. Members of the public were led to believe, I think, that hospitals are paid by the Medicare program the dollar amount that is reflected on the bill for outpatient cataract surgery. A specific reference was made to intraocular lenses; hospitals purchase intraocular lenses for $300 from the manufacturer and then charge $700 to Medicare. Medicare historically has always reimbursed hospitals "the lesser of costs or charges." This ends up, generally speaking, being 40-80% of the charges reported on the hospital's bill. The hospital purchasing the $300 lens would only be reimbursed $300 for direct cost plus any appropriate indirect costs allocated to the lens.

For example, if hospital charges added up to $3,000 for a cataract procedure including a $700 IOL (as reported on the bill), Medicare would reimburse its 80% share of the cost of care rendered to all Medicare outpatients under Part B of the program. The cost is determined upon retrospectively completing an acceptable Medicare cost report. The other 20% of charges is the deductible which in most instances is covered by co-insurance. In the example referred to above, the hospital can anticipate receiving $600 from the patient (20% of the billed charges for the Medicare deductible) and 80% of the costs from the Medicare program ($1,320, for example, if the ratio of costs to charges is 60%). The remaining $1,180 is a contractual discount under the Medicare program. Hospital charges as recorded on the bill are somewhat irrelevant, because the Medicare program will only pay for 80% of reimbursable costs; thus $3,000 of charges result in $1,920 of reimbursement!

Cost reductions can never improve a hospital's bottom line -- for this reason, there has never been an incentive to lower costs under historical cost reimbursement prior to the DRGs. The lower your costs, the lower your Medicare reimbursement! With the fixed price method of reimbursement, hospitals now

The Honorable Claude Pepper
August 6, 1985
Page 2

have an incentive to lower costs -- recognizing that a positive bottom line can hopefully occur.

I trust this clarifies your understanding of this important matter.

On a related issue, eye hospitals applaud your efforts to establish a fixed price for outpatient surgery. We strongly believe, however, that there will need to be three rates--one for the inpatient DRGs (as it now exists); a second rate for hospital-based ambulatory surgery, and a lesser third rate for freestanding ambulatory facilities. Senator Durenberger's bill (S.1489) attempts to equalize the price for all outpatient surgery. This would be acceptable if hospitals could somehow remain open only 40 hours per week instead of 168 hours! Furthermore, hospitals incur high stand-by costs for (i.e. 24-hour emergency room) to meet licensure, Medicare, Medicaid requirements as well as Joint Commission standards.

Unfortunately, most eye hospitals will be bankrupt in five years due to equal rate provisions of S.1489, assuming, of course, this bill passes as written. Almost one half of the patients coming to an eye hospital do so for cataract surgery. We generallly see the elderly patient with many other medical problems and risks. We are in a position to manage the intra-operative and post-operative complications that do arise with the less healthy elderly person. The free-standing facility cannot adequately accomodate the patient who has the multiple medical problems that, in our opinion, unfortunately arise as a part of the aging process. Hopefully, this part of Senator Durenberger's bill will be altered.

Thanks again for your interest.

Sincerely,

Gordon Smith
American Association of Eye and Ear Hospitals

GS:lw

cc:

Senator David Durenberger
Mr. Richard Kusserow
Representative Edward Roybal
Representative Mary Rose Oakar
Mr. Frank E. Young
Representative Pete Stark
Ms. Karen Lloyd
Mr. Frank Samuels, Jr.
Mr. Ron Schwartz

APPENDIX 3

PREPARED STATEMENT OF ALAN R. MCMILLEN, EXECUTIVE VICE PRESIDENT, COOPER-VISION, INC.

Mr. Chairman and Members of the Committee:

CooperVision, Inc. develops, manufactures, and markets a broad range of eye care products for the ophthalmic and optometric markets. We thank you for providing us with an opportunity to present our views regarding intraocular lens (IOL) marketing and reimbursement practices and their impact on the Medicare program. These remarks are intended to supplement the information provided to your staff in several meetings conducted since March and our response to the questionnaire submitted to the Committee last week.

It is unfortunate that federal health policy-makers, ophthalmologists and their organizational representatives, and the ophthalmic industry are meeting today under these circumstances. We have a great deal for which to be proud. As a result of our partnership -- the physician as skilled surgeon and the manufacturer as source of innovative technology -- this nation's elderly are receiving the finest ophthalmic care in the world. Refined surgical techniques, like small-incision surgery, and significant technological developments, including IOLs and equipment like the Kelman Phaco-Emulsifier and the YAG laser, have led to high-quality, rapid visual restoration following cataract surgery for millions of patients.

These forces which have brought about a revolution in eye care are convening under a cloud of suspicion concerning, not the effectiveness or utilization of this sight-saving technology, but, rather, irregularities in the payment for these services. CooperVision officials have, on our own volition, met with the Committee's staff on several occasions and have attempted to cooperate with this investigation in every respect. We are aware that the Committee has amassed considerable information, some quantifiable and some anecdotal, regarding abuses in the marketing practices of some IOL manufacturers and the reimbursement practices of some surgeons.

It is in the face of these revelations of inappropriate conduct that we should not lose sight of the fact that the vast majority of representatives of the ophthalmic industry and the ophthalmology community are forthright businessmen and health professionals who are attempting to facilitate the provision of the highest quality health care and survive in an increasingly competitive health care delivery system. In this environment, Congress, the Department of Health and Human Services, the ophthalmology community, and the ophthalmic industry must dedicate itself to the constructive exercise of developing remedies which promote:

(1) compliance with the letter and spirit of federal policy;

(2) continued innovation in technology; and

(3) a competitive environment in which health costs will be reduced without compromising the quality of care delivered.

CooperVision's Products and Programs

As noted above, CooperVision develops, manufactures and sells a broad range of eye care products for the ophthalmic and optometric markets. In terms of breadth and depth of product line, it is one of the leading companies in the professional eye care products field. CooperVision's products can be broadly categorized into: a line of sophisticated surgical and diagnostic instruments and equipment which are used extensively by eye care specialists, including the Dicon Auto Perimeter, a microprocessor-based diagnostic instrument used in the detection and measurement of visual field defects; the Kelman Phaco-Emulsifier, the world's leading ultrasonic surgical device for cataract surgery; clinical lasers; specular microscopes; diagnostic imaging equipment; a line of IOLs; soft contact lenses, including Permalens, the largest selling extended wear contact lens in the world; a broad line of contact lens care solutions which are marketed over-the-counter; and a line of ophthalmic pharmaceuticals. In essence, CooperVision is among the premier manufacturers and suppliers of ophthalmic surgical products, ranging from intraocular lenses to space-age lasers.

Because of CooperVision's product line, the company has chosen a marketing strategy designed to allow us to take competitive advantage of this diversity while providing our customers with the ability to continually invest in state-of-the-art, high-technology capital equipment without the bite of significant up-front capital expense. Through these cross-merchandizing efforts, we are able to provide our customers with volume purchase discounts and methods of financing which embody the potential to lower the cost of health care to third-party payors, including insurance companies and Medicare. Throughout its history, CooperVision has consistently formulated its discount plans with an eye towards complying with all pertinent federal laws and regulations, including the Medicare anti-fraud and abuse sections of the Social Security Act.

Cross-merchandizing is the cornerstone of our marketing program and this approach is embodied in the Volume Incentive Purchase (VIP) Plan, an agreement whereby the customer commits to purchase a certain number of intraocular lenses within a specified period of time. In exchange for this commitment, the customer earns "earned purchase credits" at a predetermined percentage of retail price, based on the length of the VIP agreement. Typically, the earned purchase credit per IOL unit is in the $50-$75 range. The earned purchase credits may be used by the customer to either purchase CooperVision surgical equipment, supplies, or additional IOLs. These earned purchase credits only have value when purchasing the aforementioned items; they are never redeemed for cash. Indeed, a customer must specify at the time the VIP agreement is executed how the earned purchase credits will be utilized.

If the customer selects a piece of surgical equipment, the VIP agreement (which has been submitted to the Committee) clearly states which piece of equipment is being purchased by the customer, the price of the equipment, and how the customer's earned purchase credits will be utilized to pay off the equipment to CooperVision. The VIP agreement is cancellable by either party within thirty days' prior written notice. If the agreement is cancelled, or if the customer fails to satisfy his obligations, the customer is not obligated to pay for any IOLs he did not receive. However, the customer must pay CooperVision the retail price of the equipment purchased, less all actual purchase credits actually earned.

The essence of the VIP plan -- and our similarly - administered Professional Resources Plan and Value Plan -- is to enable the physician or hospital to own and utilize state-of-the-art ophthalmic surgical equipment, payable over the term of the agreement with no money down and at no interest. In an effort to provide the physician with ample information from which to secure appropriate Medicare reimbursement, our invoice specifically reflects the amount of the earned purchase credit, or discount, received with regard to the particular lens; our invoices have so reflected our discounts since March, 1983. The delineation of the discount amount is followed by a statement that "Federal Law Requires that IOL Discounts be Reflected in Costs Claimed or in Charges Made to Medicare." We believe that this program embodies the potential to effectuate cost savings to the federal government since the cost of the IOL is reduced along with the physician's or hospital's out-of-pocket expenditures and allows for continued affordable capital investment by providers and continued quality ophthalmic care for our elderly citizens.

CooperVision's Efforts to Secure Federal Guidance Regarding Its Programs

As discussed above, the aforementioned marketing programs were developed to comply with the anti-fraud and abuse provisions of the Social Security Act. From virtually the inception of the VIP plan, CooperVision sought guidance from federal officials vis-a-vis the legality of the program so that we might assure our customers of the appropriateness of entering into such an arrangement.

For example, by letter dated May 26, 1983 (which has been submitted to the Committee) we requested the opinion of the OIG with respect to the applicability of pertinent Medicare anti-fraud and abuse provisions to the VIP Plan. A meeting was held concerning this matter, attended by representatives of CooperVision, the Health Care Financing Administration, and the Office of Health Financing Integrity of the OIG. At the meeting, it was agreed by all present that the VIP Plan as presented did not likely violate the Medicare anti-fraud and abuse provisions and that a physician participating in the purchase program was likely in compliance with the anti-fraud and abuse provisions provided the physician actually reported the discounted amounts and reduced his usual and customary charge by the amount of the discount received on the IOL. As discussed above, in order to facilitate providers' ability to comply with these requirements, CooperVision has, since 1983, issued invoices which set forth the exact amount of discounts received. While we have, since 1983, had a policy of informing purchasers of their obligation to pass savings on to Medicare, we have even modified our invoice to specifically denote this obligation.

Despite the fact that all parties to the meeting were in agreement as to the legality of our program, the OIG was precluded from confirming this in writing. As a result, CooperVision was unable to unequivocably assure purchasers of its IOLs that the discount arrangement complied with legal requirements. The inability of the OIG to formally "sanction" this approach to the statutory requirement that discounts be "reflected" in charges made to the Medicare program had the effect of bypassing an opportunity to set a standard for the conduct of business between suppliers and providers -- an opportunity which, we believe, would have yielded significant savings to the Medicare program and would have discouraged the conduct of potentially abusive and fraudulent transactions.

Moreover, the inability of the OIG to render advisory opinions on arrangements brought to its attention, in conjunction with the lack of enforcement of the Medicare anti-fraud and abuse provisions by the Justice Department, clearly penalizes suppliers, that have taken the proscriptions contained in the statute seriously. It is indeed conceivable that, had the government provided appropriate guidance to providers and industry two years ago, we might not be discussing a number of these issues in this forum today. Accordingly, we have recommended that the Committee adopt, as part of its legislative package, a number of modifications to the legal authorities through which the Medicare anti-fraud and abuse provisions are enforced.

Recommended Reforms to the Anti-Fraud and Abuse Authorities

Due to the very broad statutory language of the Medicare anti-fraud and abuse provisions and to the inability of the OIG or the Department of Justice to provide any definitive interpretation of these provisions, industry and providers are frustrated in the lack of assurance that the discounts and price reductions which are being offered are consistent with the law.

In order to assist manufacturers and providers comprehend the parameters of the anti-fraud and abuse provisions and adapt their marketing and reimbursement practices accordingly, we recommend the following:

1. OIG Advisory Opinions, Cease and Desist Orders, and Civil Money Penalties. CooperVision believes that a procedure should be devised under which suppliers and providers that wish to abide by the law can obtain an advisory opinion from the OIG. Because we understand that such advisory opinions may not be able to be rendered with respect to a criminal statute, such as the current anti-fraud and abuse provisions, we would suggest that Congress amend the anti-fraud and abuse provisions to provide the OIG with authority to issue civil cease and desist orders or impose civil money penalties for violations of these provisions. It is our understanding that making this change would enable the OIG to issue interpretive regulations with respect to the meaning of language contained in the anti-fraud and abuse provisions. Although such regulations would not technically be binding with respect to criminal sanctions, they would be of considerable utility in offering suppliers and providers with some guidance concerning the interpretation of the statute.

2. Aggressive Enforcement of Criminal and Civil Provisions. We would suggest that, if provisions relating to discounts are retained, these provisions, as well as prohibitions against kickbacks, rebates, bribes, and other illegal inducements, should be rigorously enforced against providers and manufacturers, from corporate officials to sales representatives, through the imposition of civil and criminal penalties.

3. Manufacturers' Obligation to Disclose Information to Providers and Government. We would recommend that, in regulations promulgated to implement any civil anti-fraud and abuse provisions which are added to the statute, the agency make it clear that suppliers have a duty to disclose sufficient information for providers to comply with any applicable statutory disclosure requirements relating to discounts, as CooperVision has done with respect to its VIP Plan. If IOL reimbursement is to be based on invoice price, manufacturers should be required to indicate the entire amount of a discount, including those amounts attributable to equipment and supplies which are purchased as part of an IOL sales arrangement.

4. Treatment of Discounts. If the IOL reimbursement methodology is altered to enfold IOL charges into prospective payment rates, and IOLs will not be reimbursed separately, we would recommend the Committee consider repealing the anti-fraud and abuse provisions which impose criminal penalties for failure to disclose and reflect discounts. Under any form of prospective payment, providers should be encouraged to negotiate discounts.

IOL Reimbursement Methodology; Fraud and Abuse

In addition to the difficulties which providers and manufacturers have in interpreting the anti-fraud and abuse provisions of the Social Security Act, part of the problem being addressed today lies with the method through which IOLs are reimbursed by the Medicare program. Historically, Medicare has paid for IOLs on the basis of the physician's reasonable charge, i.e. the lower of his actual or customary charge, or the prevailing charge in the community. It is our understanding that, typically, Medicare pays 80% of an allowable charge of approximately $300. Under reasonable charge principles, physicians have collected from beneficiaries the 20% coinsurance on the allowable charge, and the difference between the allowable and the actual charge.

The Committee is well aware that IOL prices have eroded in recent years, due to changes in manufacturing technology and market forces. Yet, data collected by the Committee apparently indicate that, despite this erosion in IOL prices to providers, the Medicare program is not receiving a benefit in terms of reduced charges to the program. We believe that the root of this problem may be the IOL reimbursement policy administered by Medicare carriers, and we have set forth a number of legislative and regulatory options for consideration by the Committee.

In addition, the Committee is rightfully concerned with evidence demonstrating that some manufacturers are offering, and some physicians are receiving, blatantly illegal inducements to purchase IOLs, kickbacks, rebates, and bribes, and other inducements in the form of cash payments, stock, free IOLs, and free travel. No manufacturer can totally preclude the possibility that an individual sales representative might commit transgressions in overzealous sales efforts. Nonetheless, a manufacturer has an obligation to demonstrate to its employees -- through its compensation mechanism, through its training program, and through the example of company managers -- that deviations from company policy and federal law will not be tolerated.

The offer and receipt of illegal inducements do, indeed, ultimately increase Medicare expenditures. The provision of these incentives embodies the potential to cloud the provider's judgment as to which IOL is most appropriate for a given patient's clinical situation. Moreover, this behavior undermines the integrity of the Medicare program, the ophthalmology community, and the ophthalmic industry. We believe that our recommendations for Committee action will mitigate conduct which all responsible parties find offensive.

Potential IOL Reimbursement Reforms

CooperVision respectfully recommends that the Committee consider the following legislative and regulatory modifications to IOL reimbursement policy. Current reimbursement rates vary significantly from area to area, depending upon local charging practices; carriers apply different reimbursement methodologies (e.g. some carriers limit IOL reimbursement to invoice). This results in significant uncertainty for the program and providers alike. Whatever policy or policies are ultimately adopted, it should be applied uniformly by all Medicare carriers.

1. Enfold Cost of IOLs into Payments Made to Ambulatory Surgical Centers and Hospital Outpatient Departments. This approach would encourage prudent purchasing. The reductions in price are eventually passed on to the Medicare program through adjustments to prospective payment rates. Equally important, it eliminates the impact on the Medicare program of practices which arguably violate Medicare anti-fraud and abuse provisions. This approach could be supplemented by reforms which would modify the reimbursement methodology applicable to lenses purchased directly by physicians; for example, these IOLs could be reimbursed under a rate schedule or invoice plus handling charge methodology. Recommendation: This approach would appear to be the best alternative in terms of ameliorating fraudulent and abusive practices and containing

costs.

2. Limit Reimbursement for IOLs to Invoice Amount. This approach would, for the most part, preclude IOL purchasers from making a "profit" on IOLs, thereby reducing costs to Medicare. However, cost-based reimbursement does not eliminate some abusive practices. Moreover, cost-based reimbursement may not ultimately contain costs, as the Medicare program's experience with inpatient reimbursement demonstrated. Finally, limiting reimbursement to cost fails to cover the physician's administrative costs associated with procuring the IOL; this problem could be alleviated by limiting reimbursement for IOLs to invoice plus a reasonable handling charge. This approach has been adopted with respect to reimbursement for certain clinical laboratory services. Recommendation: This approach would be an acceptable alternative to charge-based reimbursement.

3. Limit Reimbursement for IOLs to a Rate Schedule. This approach would create uniformity from one geographic area to another, and could reduce overall costs to Medicare. It would also provide incentives to physicians to engage in "prudent purchasing." However, there may be, at this stage, insufficient data to derive an accurate and fair rate schedule. Moreover, a rate schedule based on current IOL prices would discourage innovation and advances in technology. Recommendation: This approach would be an acceptable alternative to charge-based reimbursement, provided that the rate schedule embodies sufficient flexibility to enable higher payment for technologically improved lenses which might have higher costs of manufacturing and research and development.

4. Maintain Current Charge-Based Reimbursement Methodology. This approach would maintain the uniformity between IOL reimbursement methodology and the reimbursement methodology used for other items and services reimbursed under Part B of the Medicare program. However, maintaining the current charge-based methodology has several disadvantages. Current fraud and abuse provisions are unclear with respect to how discounts are to be reflected in charges made to the program and enforcement of fraud and abuse provisions may be untenable. Moreover, this reimbursement methodology does not create incentives to cut costs since reimbursement is not related to the costs incurred in procuring the lens. Recommendation: This approach should not be maintained.

Conclusion

Since entering the IOL marketplace, CooperVision has been an aggressive competitor. Yet, in every way, we have attempted to comply with the spirit, as well as the letter, of Medicare policy.

CooperVision's promotional programs are scrutinized by corporate and independent legal counsel. We have presented our programs for review to the Health Care Financing Administration, the Office of the Inspector General, and other agencies.

We have presented our programs for review to interested organizations representing ophthalmologists.

We have informed providers of their obligation to reflect discounts received in charges made to the program, and have provided them with all information needed to meet this responsibility.

We have fully cooperated with the House Select Committee on Aging's important investigation on IOL marketing and reimbursement issues.

CooperVision believes that rigorous enforcement of the anti-fraud and abuse provisions and sound Medicare IOL reimbursement policy is necessary to assure that standards of integrity within the health manufacturing industry remain high, and to ensure that the medical judgment of health care providers is not impaired by undisclosed financial incentives. CooperVision will continue to assist the Committee and its staff in any appropriate manner.

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